Copy for the Elected Office (EO/US)

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

OLSSON, Gunnar
Nobel Biocare AB (publ)
P.O. Box 5190
S-402 26 Göteborg
SUÈDE

Date of mailing (day/month/year) 16 August 1999 (16.08.99)	
Applicant's or agent's file reference 4086 PCT	**IMPORTANT NOTIFICATION**
International application No. PCT/SE98/01982	**International filing date** (day/month/year) 03 November 1998 (03.11.98)

1. The following indications appeared on record concerning:

[X] the applicant [X] the inventor [ ] the agent [ ] the common representative

Name and Address	State of Nationality	State of Residence
CARLSSON, Lennart Matildebergsgatan 36 S-431 38 Göteborg Sweden	SE	SE
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address	State of Nationality	State of Residence
CARLSSON, Lennart Matildebergsgatan 36 S-431 38 Mölndal Sweden	SE	SE
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Catherine Massetti
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/306 (March 1994)

002790198

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61C 8/00 — A1

(11) International Publication Number: **WO 99/23971**

(43) International Publication Date: 20 May 1999 (20.05.99)

(21) International Application Number: PCT/SE98/01982

(22) International Filing Date: 3 November 1998 (03.11.98)

(30) Priority Data:
9704112-3 11 November 1997 (11.11.97) SE

(71) Applicant *(for all designated States except US)*: NOBEL BIOCARE AB (publ) [SE/SE]; P.O. Box 5190, S–402 26 Göteborg (SE).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: CARLSSON, Lennart [SE/SE]; Matildebergsgatan 36, S–431 38 Göteborg (SE). ENGMAN, Fredrik [SE/SE]; Häggvägen 19, S–435 37 Mölnlycke (SE). FROMELL, Roger [SE/SE]; Malörtsvägen 11, S–449 33 Nödinge (SE). TORNÉUS, Lars [SE/SE]; Riabergsvägen 7B, S–430 30 Frillesås (SE).

(74) Agent: OLSSON, Gunnar; Nobel Biocare AB (publ), P.O. Box 5190, S–402 26 Göteborg (SE).

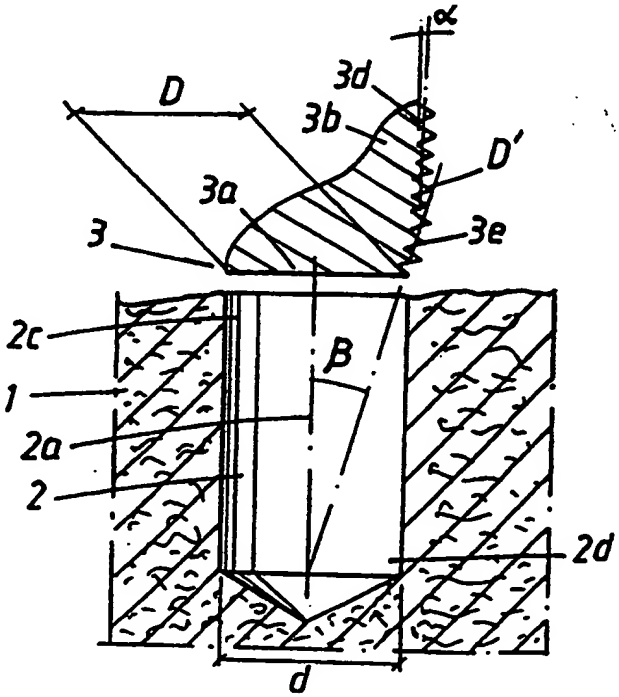
(81) Designated States: AU, BR, CA, IL, JP, MX, NO, PL, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.
In English translation (filed in Swedish).

(54) Title: ARRANGEMENT FOR OBTAINING RELIABLE ANCHORING OF A THREADED IMPLANT IN BONE

(57) Abstract

In an arrangement for obtaining reliable anchoring of a threaded implant (3) in dentine, a hole (2) is made in the bone substance. In the side wall (2b) of the hole it is possible to establish an internal threading which can cooperate with an external threading (3d) on the implant. The implant threading is arranged to force the bone substance out in essentially radial directions as a function of the extent to which the implant is screwed into the hole. The threading is arranged to effect greater forcing out of the bone substance at the outer parts of the hole than at the inner parts of the hole. The degree of forcing out is adapted in relation to the softness of the bone in order to achieve the reliable anchoring. Along at least part of the longitudinal direction of the implant, the implant threading can be given a non–circular configuration for the purpose of obtaining improved rotational stability in soft/weak bone. The implant can also have two or more thread spirals/thread entries which shorten the time for screwing the implant into the hole and additionally offer tight threading which permits effective integration with the bone substance during the healing–in process.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/01982

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61C 8/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0282789 A2 (GRAFELMANN, HANS L. PROF.), 21 Sept 1988 (21.09.88) --	1-6
X	EP 0530160 A1 (NOBELPHARMA AB), 3 March 1993 (03.03.93) --	1-6
X	WO 9306786 A1 (RUSSO, GIANNI), 15 April 1993 (15.04.93) --	1-6
X	WO 9725933 A1 (IMPLANT INNOVATIONS, INC.), 24 July 1997 (24.07.97) --	1-11

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 February 1999	06 -03- 1999
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. + 46 8 666 02 86	Authorized officer Jack Hedlund

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/01982

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0263809 A2 (PUTZ, ERICH, DR.), 13 April 1988 (13.04.88) -- --------	1,12-15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/SE 98/01982

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0282789 A2	21/09/88	SE 0282789 T3	
		DE 3708638 A	29/09/88
		US 4863383 A	05/09/89
EP 0530160 A1	03/03/93	AT 136207 T	15/04/96
		CA 2076939 A	28/02/93
		DE 69209592 D,T	19/09/96
		DK 530160 T	05/08/96
		ES 2085612 T	01/06/96
		GR 3019974 T	31/08/96
		JP 2627385 B	02/07/97
		JP 5228162 A	07/09/93
		SE 468154 B,C	16/11/92
		SE 9102451 A	16/11/92
		US 5269685 A	14/12/93
WO 9306786 A1	15/04/93	IT 1253481 B	08/08/95
		IT MO910150 D	00/00/00
WO 9725933 A1	24/07/97	AU 1531697 A	11/08/97
		BR 9704618 A	09/06/98
		EP 0828460 A	18/03/98
		NO 974289 A	17/09/97
EP 0263809 A2	13/04/88	AT 252786 A	15/09/87
		AT 385409 A,B	25/03/88

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 4086 PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE98/01982	International filing date *(day/month/year)* 03.11.1998	Priority date *(day/month/year)* 11.11.1997
International Patent Classification (IPC) or national classification and IPC7 A 61 C 8/00		
Applicant Nobel Biocare AB (publ) et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
04.06.1999	13.03.2000
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Telex 17978 PATOREG-S Facsimile No. 08-667 72 88	Authorized officer Jack Hedlund/Els Telephone No. 08-782 25 00

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE98/01982

I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

☐ the international application as originally filed.

☒ the description, pages 1-16, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____.
pages _____, filed with the letter of _____.

☒ the claims, Nos. _____, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. 1-12, filed with the letter of 01.12.1999,
Nos. _____, filed with the letter of _____.

☒ the drawings, ~~sheets~~/fig 1-18, as originally filed,
~~sheets~~/fig _____, filed with the demand
~~sheets~~/fig _____, filed with the letter of _____,
~~sheets~~/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, ~~sheets~~/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE98/01982

V. Resoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-12	YES
	Claims		NO
Inventive step (IS)	Claims	1-12	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

2. Citations and explanations

The claimed invention relates to a threaded implant for obtaining reliable anchoring in bone substance.

The object of the invention is to reduce the friction between bone and implant on insertion of the implant.

This is achieved by an implant, in which the threading is arranged to force the bone substance out in essentially radial directions as a function of the extent to which the implant is screwed into the hole. The implant also has two or more thread spirals / thread entries.

New, amended claims have been filed 01.12.1999. The new claim 1 substantially corresponds to previous claims 1 (alternatives a + c), 3, 6 and 12. The claims are now also directed to a "Threaded implant for obtaining..." instead of "Arrangement for obtaining...". The sub-claims substantially correspond to previous claims 2, 4, 5, 7-11 and 13-15. Specifically, the implant threading has a slight conicity, which cooperates with a cylindrical hole, and effects greater forcing out of the bone at the outer parts of the hole than at the inner parts. The conical threading also has two or more thread spirals that shortens the time for inserting the implant but still provides a tight threading which permits effective bone integration and counteracts deformation or breaking-up of fine bone trabeculae when inserted in soft/weak bone.

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V

The following documents are cited in the search report:

(D1) EP 0282789 A2
(D2) EP 0530160 A1
(D3) WO 9306786 A1
(D4) WO 9725933 A1
(D5) EP 0263809 A2

(D1) - (D4) relates to implants having a threading, which is arranged to force the bone substance out in radial directions. Greater forcing out is effected at the outer parts of the hole than at the inner parts of the hole.

The implant in (D4) is given a non-circular cross section.

(D5) relates to an implant having two thread spirals.

However, none of the documents mention anything about an implant having threading with a slight conicity and also having two or more thread spirals, and none of the documents relates to the problems when inserting an implant into soft/weak bone tissue.

Therefore, the cited documents only disclose the general state of the art, which is not considered to be of particular relevance, and the invention claimed 01.12.1999 is considered to fulfil the requirements of novelty, inventive step and industrial applicability.

09/509869
PCT/SE98/01982

PCT/SE98/01982

PATENT CLAIMS

1. Threaded implant (3) for obtaining reliable anchoring in bone substance (1), preferably in the jaw-bone, in the human body, the bone substance being provided with a hole (2) in whose side wall (2b) it is possible to establish an internal threading (1a) which can cooperate with an external threading (3d, 3d´) on the implant for reliable anchoring and healing-in of the implant in the bone substance, characterized in that the implant threading is arranged, particularly in the case of soft bone substance, to force the bone substance out in essentially radial directions (R) as a function of the extent to which the implant is screwed into the hole, that the implant threading has a slight conicity which extends along most or part of the length (L) of the implant and which cooperates with a circular cylindrical hole (2) in the bone (1) to effect greater forcing out of the bone substance at the outer parts (2c) of the hole than at the inner parts (2d) of the hole, the degree of forcing out being adapted in relation to the softness of the bone substance in order to achieve the reliable anchoring, and that said conical threading comprises two or more thread spirals (thread entries) which, despite shortening the time for screwing the implant into the hole, provide a tight threading which permits effective integration with the bone substance during the healing-in process and counteracts deformation or breaking-up of fine bone trabeculae which surround the hole in the bone.

2. Implant according to claim 1, characterized in that the implant threading is arranged to ensure

that the pressure (P, P´) between the bone substance and the implant has essentially a constant or slightly increasing value during the greater part of the operation of screwing the implant into the hole.

3. Implant according to claim 1 or 2, characterized in that the front portion (tip) (3a) of the implant is designed with a conical thread (3e) which has a conicity essentially exceeding the conicity of the slightly conical thread (3d).

4. Implant according to claim 3, characterized in that the conicity of the slightly conical thread is chosen between 0.1 - 0.4 mm or has an angle of inclination (α) of about 0,5 - 2°, and/or the thread conicity of the thread at the said portion/tip (3a) is of the order of 0.4 - 0.8 mm or with an angle of inclination (β) of about 10 - 15°, and the portion/tip has a length or height (h) of about 10 - 30% of the length (L) of the threaded part of the implant.

5. Implant according to claim 1, characterized in that the implant threading along at least part of the longitudinal direction of the implant is given a noncircular or eccentric configuration (8a-8i) for the purpose of obtaining improved rotational stability of the implant in the recently inserted state or the incorporated state of the implant in soft/weak bone.

6. Implant according to claim 5, characterized in that the implant is arranged with a minimum diameter (D´) which corresponds to or is slightly greater, for example 1 - 5% greater, than the diameter (d) of the hole.

7. Implant according to claim 1 or any of claims 5-6, characterized in that the tip or the free end of the implant has a circular or concentric thread (3e) which merges gradually into a non-circular or eccentric thread on the remaining part or parts of the implant.

8. Implant according to claim 1 or any of claims 5-7, characterized in that the peripheris of the different non-circular or eccentric thread cross-sections have bevelled corners (12) in order to avoid sharp corners.

9. Implant according to claim 1 or any of claims 5-8, characterized in that the non-circularity is arranged such that areas of maximum diameter are displaced in the peripheral direction from one thread turn (10) to the next thread turn (11).

10. Implant according to claim 1, characterized in that the number of thread spirals/thread entries is two, three or four.

11. Implant according to claim 10, characterized in that the number of thread spirals/thread entries is adapted to the number of cutting edges (5a, 5b, 5c, 5d) so that symmetrical cutting forces are obtained.

12. Implant according to claim 10 or 11, characterized in that two thread spirals are arranged on the implant together with two or four cutting edges, or in that three thread spirals are arranged together with three cutting edges, etc.

02-12-1998

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No. PCT/SE98/01982

International Filing Date 03-11-1998

The Swedish Patent Office
PCT International Application

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 4086 PCT

Box No. I TITLE OF INVENTION Arrangement for obtaining reliable anchoring of a threaded implant in bone.

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

Nobel Biocare AB (publ)
Box 5190
S-402 26 GÖTEBORG
Sweden

☐ This person is also inventor.

Telephone No. +46(0)31 818800

Facsimile No. +46(0)31 163152

Teleprinter No.

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

CARLSSON, Lennart
Matildebergsgatan 36
S-431 38 GÖTEBORG
Sweden

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below ~~is hereby~~/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

OLSSON, Gunnar
Nobel Biocare AB (publ)
Box 5190
S-402 26 GÖTEBORG
Sweden

Telephone No. +46(0)31 818929

Facsimile No. +46(0)31 163152

Teleprinter No.

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

PCT/SE98/01882
03-11-1998

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

ENGMAN, Fredrik
Häggvägen 19
S-435 37 MÖLNLYCKE
Sweden

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☒ the United States of America only
- ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

FROMELL, Roger
Malörtsvägen 11
S-449 33 NÖDINGE
Sweden

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☒ the United States of America only
- ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

JÖRNEUS, Lars
Riabergsvägen 7B
S-430 30 FRILLESÅS
Sweden

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☐ the United States of America only
- ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☐ the United States of America only
- ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

T. SE 98/01982
03-11-1998

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes: at least one must be marked)*:

Regional Patent

- ☐ AP **ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☐ EA **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☐ OA **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

- ☐ AL Albania
- ☐ AM Armenia
- ☐ AT Austria
- ☒ AU Australia
- ☐ AZ Azerbaijan
- ☐ BA Bosnia and Herzegovina
- ☐ BB Barbados
- ☐ BG Bulgaria
- ☒ BR Brazil
- ☐ BY Belarus
- ☒ CA Canada
- ☐ CH and LI Switzerland and Liechtenstein
- ☐ CN China
- ☐ CU Cuba
- ☐ CZ Czech Republic
- ☐ DE Germany
- ☐ DK Denmark
- ☐ EE Estonia
- ☐ ES Spain
- ☐ FI Finland
- ☐ GB United Kingdom
- ☐ GE Georgia
- ☐ GH Ghana
- ☐ GM Gambia
- ☐ GW Guinea-Bissau
- ☐ HR Croatia
- ☐ HU Hungary
- ☐ ID Indonesia
- ☒ IL Israel
- ☐ IS Iceland
- ☒ JP Japan
- ☐ KE Kenya
- ☐ KG Kyrgyzstan
- ☐ KP Democratic People's Republic of Korea
- ☐ KR Republic of Korea
- ☐ KZ Kazakhstan
- ☐ LC Saint Lucia
- ☐ LK Sri Lanka
- ☐ LR Liberia
- ☐ LS Lesotho
- ☐ LT Lithuania
- ☐ LU Luxembourg
- ☐ LV Latvia
- ☐ MD Republic of Moldova
- ☐ MG Madagascar
- ☐ MK The former Yugoslav Republic of Macedonia
- ☐ MN Mongolia
- ☐ MW Malawi
- ☒ MX Mexico
- ☒ NO Norway
- ☐ NZ New Zealand
- ☒ PL Poland
- ☐ PT Portugal
- ☐ RO Romania
- ☐ RU Russian Federation
- ☐ SD Sudan
- ☐ SE Sweden
- ☐ SG Singapore
- ☐ SI Slovenia
- ☐ SK Slovakia
- ☐ SL Sierra Leone
- ☐ TJ Tajikistan
- ☐ TM Turkmenistan
- ☐ TR Turkey
- ☐ TT Trinidad and Tobago
- ☐ UA Ukraine
- ☐ UG Uganda
- ☒ US United States of America
- ☐ UZ Uzbekistan
- ☐ VN Viet Nam
- ☐ YU Yugoslavia
- ☐ ZW Zimbabwe

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

- ☐ .....
- ☐ .....

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)*

PCT SE 98/01982
03 -11- 1998

Box No. VI PRIORITY CLAIM ☐ Further priority claims are indicated in the Supplemental Box.

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1) 11/11/97 11 Nov. 1997	97 04112-3	SE		
item (2)				
item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s): (1)

* *Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)*: ISA / SE

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority)*:

Date *(day/month/year)*	Number	Country *(or regional Office)*
11 November 1997	SE97/01501	SE

Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following **number of sheets**:

request	4	✓
description (excluding sequence listing part)	16	✓
claims	4	✓
abstract	1	✓
drawings	4	✓
sequence listing part of description		
Total number of sheets	29	✓

This international application is **accompanied by** the item(s) marked below:

1. ☐ fee calculation sheet
2. ☐ separate signed power of attorney
3. ☒ copy of general power of attorney; reference number, if any: 243
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☐ other *(specify)*: ITS-report

Figure of the drawings which should accompany the abstract: 1b

Language of filing of the international application: Swedish

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Nobel Biocare AB (publ)

Gunnar Olsson

/ Gunnar Olsson / AGENT

For receiving Office use only

1. Date of actual receipt of the purported international application: 03 -11- 1998
2. Drawings: ☒ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority (if two or more are competent): ISA / SE
6. ☐ Transmittal of search copy delayed until search fee is paid.

For International Bureau use only

Date of receipt of the record copy by the International Bureau: 19 NOVEMBER 1998 (19.11.98)

See Notes to the request form

PCT/SE 98/01982
03 -11- 1998

BENÄMNING

Anordning för att åstadkomma tillförlitlig förankring av gängförsett implantat i ben.

TEKNISKT OMRÅDE

Föreliggande uppfinning avser en anordning för att åstadkomma tillförlitlig förankring av gängförsett implantat i ben, företrädesvis tandben, i människokroppen. Ifrågavarande ben är därvid försett med upptaget hål i vars sidovägg är etablerbar en invändig gängbildning som är samverkbar med en utvändig gängbildning på implantatet för implantatets tillförlitliga förankring och fastläkning i benet.

TEKNIKENS STÅNDPUNKT

Implantat med gängor, t.ex. självgängande sådana, för isättning/iskruvning i upptagna hål i ben/tandben förekommer i stort antal och utföranden på den öppna marknaden och inom patentlitteraturen. Så t.ex. kan hänvisas till den av samma sökanden som innevarande patentansökan inlämnade svenska patentansökningen 9603091-7.

Det är därvid känt att föreslå olika gängutformningar på implantat. Så t.ex. är det förut känt att utnyttja implantat med konade gängor och att välja olika koniciteter på ett och samma implantat. Hålupptagningsförfaranden i ben/tandben är även väl förut kända. Rent allmänt kan härvid hänvisas till tandbehandling enligt Brånemark System®

Vissa av de gängade implantaten är cylindriska, medan andra kan uppvisa nämnda koniska utföranden för att

PCT/SE 98/01982
03 -11- 1998

efterlikna den tandrot som de skall ersätta. Insättning av implantat i benet sker i förborrade hål i käkbenet. För cylindriska implantat borras ett cylindriskt hål och för koniska implantat prepareras ett koniskt hål. Nämnda metod enligt Brånemark System® innebär att man fäster skruvformade implantat i käkbenet. Efter en inläkningsperiod, normalt om 3-6 månader, har benet vuxit i direkt kontakt med implantatet och detta kan därefter användas för att uppbära en protetisk rekonstruktion. Detta utföres oftast genom att s.k. distanselement ansluts till implantatet, vilket kan ske med ett skruvförband. Uppe på distansen anslutes därefter en överföringshätta vid den s.k. avtryckstagningen och därefter kan den färdiga protetiska rekonstruktionen appliceras till distansen.

Genom de kända metoderna är det förut känt att man erhåller goda långtidsresultat om osseointegrationen mellan benet och implantatet kan ske med tät profil och liten stigning på ifrågavarande gängor. Under osseointegrationen växer benvävnaden i direktkontakt med implantatet. Vid installationen av implantaten borrar man med stor precision nämnda hål i benet. Det är därvid förut känt att använda fastdragningsverktyg som roterar med ca 20-25 varv/minut.

Genom WO 97/25933 (PCT/US97/00332) är det förut känt att speciellt i anslutning till hårt tandben föreslå att den gängan uppbärande kroppen skall göras orund (osymmetrisk) i sitt tvärsnitt.

Syftet med orundheten är här att minska friktionen mellan ben och implantat vid insättning av implantatet. Detta har betydelse främst vid hårt ben.

SE 98/01982

03 -11- 1998

REDOGÖRELSE FÖR UPPFINNINGEN

TEKNISKT PROBLEM

Problemet med att utnyttja cylindriska implantat i cylindriska hål är att den gänga som oftast skapas av implantatets självgängande spets slits alltefter som implantatet skruvas i och med detta slitage vidgas gängan framförallt vid hålets ingång/mynning i benet. Detta medför att implantatet kommer att få en något lös förankring framförallt i dåligt/mjukt ben, vilket innebär att implantatet får en undermålig initial stabilitet. Vid utnyttjandet av koniska implantat med konisk preparation är ett av de största problemen den värmeutveckling som sker vid den koniska preparationen. Eftersom ett konisk borr skär längs hela periferin genereras en förhållandevis hög värme, vilken negativa effekt förstärks ytterligare av att skärgeometri på ett koniskt borr blir sämre på grund av att låga yttryck uppträder på det koniska borrets periferi. Detta medför att borret inte kan skära ordentliga spånor utan hellre skaver bort ben, vilket medför en hög värmegenererande effekt. Denna värme kan skada benet och kan medföra att benet närmast det borrade hålet dör. Detta minskar möjligheterna till framgångsrik osseointegration drastiskt. Föreliggande uppfinning har till ändamål att lösa bl.a. ovanstående problematik.

Nämnda utnyttjande av skruvförband på implantat innebär att man skruvar åt och lossar skruvar. Detta utgör ett relativt stort riskmoment eftersom implantatet utsättes för brytbelastningar som medför att implantatet riskerar att vridas ur sitt läge. Detta gäller speciellt om implantaten är applicerade i ben av dålig/mjuk kvalitet. Ovanstående lossdragningsproblem är speciellt utpräglat vid implantat med en gänga som är cirkulärsymmetrisk. Visserligen kan man vid de

PCT SE 98/01982
03 -11- 1998

flesta gängade implantat vid spetsen anordna urtag som är avsedda både för att skära gängor och att bidra till rotationsstabiliteten. Det förekommer även implantat med tvärgående hål avsedda för beninväxt. Gemensamt för dessa kända konstruktioner är att urtagen och hålen är relativt små sett i relation till implantatets gängade area. Genom att urtagens eller hålens yta är liten sker deformation eller sönderbrytning av det inväxta benet lätt vid vridbelastning. Dessutom är hålen och urtagningarna belägna längst fram i spetsen där oftast benets kvalitet (hårdhet) är sämre. Det finns dessutom en inneboende svaghet genom att hålen och urtagen minskar implantatets gängade area. Det kan härvid framhållas att det är väsentligt att erhålla största möjliga gängade area för effektiv överföring av den funktionella belastningen från tandprotesen eller tandbron ner till benet. Detta gäller speciellt vid mjukt ben.

Ett annat problem med de kända implantaten är att respektive implantat, speciellt vid dålig/mjuk benkvalitet, inte sitter tillräckligt stabilt i benet direkt efter insättningen. När så är fallet kan det uppstå mikrorörelser mellan implantatet och den omgivande benvävnaden t.ex. då benet böjs, vilket kan ske då benet utsätts för tuggbelastningar eller om patienten har en konventionell tandprotes som trycker på tandköttet ovanför implantatet. Det är då viktigt att implantatet har tillräcklig initial stabilitet. Tidigare kända lösningar har bestått av att införa förändringar på ytan, t.ex. att använda beläggning med hydroxylapatit eller öka implantatets ytråhet och på så sätt erbjuda ökad initial stabilitet och eventuellt bättre inläkning av det omgivande benet. En stor nackdel med de föreslagna lösningarna har varit att det inte går att förutse implantatets lyckandefrekvens på lång sikt. Det finns åtskilliga vetenskapligt publi-

PCT/SE 98/01982
03 -11- 1998

cerade artiklar om undermåliga långtidsresultat med implantat med grov yta eller med beläggningar.

En viktig förutsättning för att kunna utöva de ovan omnämnda metoderna är att skapa förutsättningar för att få direkt benkontakt med implanatet under fastläkningsprocessen. Det är därvid väsentligt att en skonsam kirurgi kan föreligga under installationen av implantaten. Hålet för implantatet skall borras med stor precision och det är därvid av yttersta vikt att temperaturen i benet ej blir för hög. Dessa krav har hitintills inneburit att både borrning och installation av implantatet utförts med låg hastighet på ifrågavarande hålupptagnings- och fastdragningsverktyg. Den rotationshastighet som normalt används vid installation av implantaten är 20-25 varv/minut. Detta innebär att tiden för att installera ett implantat kan uppgår till 1 minut eller mer. Under denna tid krävs det att kirurgen som sätter in implantatet är mycket stadig på hand så att de fina bentrabekler som omger hålet ej deformeras eller bryts sönder. Vickrörelser i verktyget under idragningen medför risker för att deformation och sönderbrytning uppkommer. Man har försökt lösa detta problem genom att förse implantatet med ökad gängstigning. Normalt innebär detta att gängans profil är större och gängan blir glesare. Denna glesare gänga är ofördelaktig i flera avseenden. Det blir färre gängor och därmed en ökad spänningskoncentration kring varje gängtopp och dessutom med en grövre gängprofil större skillnad mellan ytter- och innerdiameter, vilket för en given ytterdiameter på implantatet leder till ett mekaniskt svagare implantat. En alternativ lösning till detta problem skulle vara att öka varvtalet på fastdragningsverktyget så att implantatet snabbare roterar in i position. Detta förfarande har också nackdelar. Temperaturen i benvävnaden kan bli för hög. En annan faktor att ta i

beaktande är att ett stort antal på marknaden befintliga borr- och fastdragningsmaskinsutrustningar arbetar med ett varvtal som är begränsat till 20-25 varv/minut.

Uppfinningen avser att lösa även de sistnämnda problemen.

LÖSNINGEN

Det som huvudsakligen kan anses vara kännetecknande för en anordning enligt uppfinningen är att denna uppfyller ett eller en kombination av två eller samtliga av följande särdrag:

a) att implantatets gängbildning är anordnad, speciellt vid mjukt benmaterial, att förorsaka en av implantatets iskruvningsgrad i hålet beroende utpressning av benmaterialet i väsentligen radiella riktningar, att implantatets gängbildning är anordnad att förorsaka en större utpressning av benmaterialet vid hålets yttre delar jämfört med hålets inre delar, och att utpressningsgraden därvid är relationsställd till benmaterialets mjukhetsgrad för att effektuera den tillförlitliga förankringen,

b) att implantatets gängbildning åtminstone utefter en del av implantatets längdriktning är tilldelad ocirkulär eller excentrisk utformning i syfte att erhålla förbättrad rotationsstabilitet i mjukt/dåligt ben,

c) att implantatet är försett med gängbildning som innefattar ett eller flera partier med två eller flera gängspiraler eller gängingångar som trots förkortning av iskruvningstiden för implantatet i hålet uppvisar en tät gängbildning som möjliggör effektiv integration med benmaterialet under fastläkningen/osseointegrationen.

I utföringsformer enligt a) ovan är implantatets gängbildning anordnad att åstadkomma att trycket mellan benmaterialet och implantatet uppvisar väsentligen konstant eller endast något ökande värde under den väsentligaste delen av iskruvningsförloppet. Implantatets gängbildning kan vidare innefatta ett parti, vars gänga är svagt koniskt avsmalnande mot implantatets fria ände eller spets och sträcker sig utefter åtminstone de väsentligaste delarna av implantatets längd. Implantatets främre parti eller spets kan i en utföringsform utföras med en sig tilldelad konisk gänga som har en starkare konicitet än implantatets övriga gänga eller gängdelar. Koniciteten mätt över diametern på den svagt konade gängan kan väljas inom området 0,1 till 0,4 mm eller uppvisa en lutningsvinkel av ca 0,5 - 2° Gängkoniciteten på partiets eller spetsens gänga kan vara av storleksordningen 0,4-0,8 mm eller utföras med en lutningsvinkel av ca 10-15°. Spetsen kan uppvisa en längd som är 10-30% av längden på implantatets totala gänga. I en föredragen utföringsform användes ett implantat med svag konicitet på den huvudsakliga delen av dess gänga i en cirkulärcylindrisk hålupptagning i benet.

I anslutning till särdragen enligt b) ovan är ocirkulariteten eller excentriciteten anordnad att väsentligen öka implantatets rotationsstabilitet i implantatets nyss isatta (initiala) eller fastväxta läge. Ocirkulariteten eller excentriciteten kan vidare anordnas att motverka effekten av sönderbrytning av hålets gänga vid hålets inre delar. Implantatet är i en utföringsform anordnad med en minsta diameter eller tvärsnittsbredd som motsvarar eller är endast något större, t.ex. 1-5% större, än diametern på benets/ /tandbenets hål. Med implantatets minsta diameter menas då här gängans kärndiameter vid minsta diametern på det svagt koniska partiet. Implantatets spets eller

PCT SE 98/01982
03 -11- 1998

fria ände uppvisar en rund eller koncentrisk gänga som sett från den fria änden successivt övergår till en orund eller excentrisk gänga på implantatets övriga del eller delar. Orundheten anordnas därvid så att inga skarpa hörn föreligger, utan endast avfasade hörn. Orundheten kan även anordnas så att områden med maximal diameter förskjuts i perifiell led från ett gängvarv till nästa gängvarv. Orundheten kan anordnas på den gängüppbärande kroppen och/eller på respektive gängas ytterperiferi.

Utföringsformer enligt c) i ovanstående kan utgöras av att anordningen är anordnad att motverka deformationer eller sönderbrytning av fria bentrabekler som omger hålet i benet. Ytterligare särdrag för utföringsformer kan vara att antalet gängspiraler kan väljas i beroende av önskad iskruvningstid för implantatet i hålen och så t.ex. kan antalet gängspiraler vara två, tre eller fyra. Ytterligare särdrag för utföringsformer är att antalet gängspiraler anpassas till antalet på implantatet anordnade skär så att symmetriska skärkrafter erhålles.

FÖRDELAR

Genom det i ovanstående föreslagna erhålles implantat med mycket goda egenskaper. Implantatet kan anordnas med väsentligt förbättrade startegenskaper som medför att implantatet lätt "tar gängor" även om det initiala i benet upptagna hålet är litet i förhållande till implantatets diameter. Genom att trycket mellan implantatet och gängan i benet inte minskar möjliggörs en successivt ökande framdrivningskraft vilket motverkar tendenser till att dra sönder de understundom sköra bengängorna. Den initiala stabiliteten för implantatet i hålet kan förbättras eftersom benets elasticitet gör att benvävnaden helt

SE 98/01982
03 -11- 1998

eller delvis kan fjädra tillbaka in i de grundare partierna på fixturen. Efter inläkning då nytt och oftast kraftigare ben växt i direktkontakt med implantatet sitter detta mycket stabilt i rotationsled eftersom man vid lossvridning av implantatet måste bryta sönder stora benområden sett i relation till implantatets totala yta. Detta har betydelse speciellt vid mjuka benkvaliteter. Implantatsgängan kan utföras med tvärsnitt som är utformade som polygoner, företrädesvis med något avrundade hörn, eller en något 3-, 5-, 7-kantig geometri, jämför liktjocking. Denna typ av orund geometri har egenskapen att den har en skenbart väsentligen konstant diameter när den mäts med skjutmått eller mikrometer. För att förbättra implantatets startegenskaper så att implantatet lätt tar gängor vid början av iskruvningen kan implantatet förses med gängskär. Dessa kan anordnas så de skär vid implantatets största diameter vilket kan vara lämpligt då implantatet är koniskt och man tack vare koniciteten får en klämeffekt.

Speciellt viktigt vid mjukt ben är att kombinera orundheten med en konicitet. Denna konicitet kan vara utförd så att basdiametern successivt ökar, eller alternativt att orundheten ökar med bibehållen eller endast något ökande "innerdiameter". Kombinationen av orundhet och konicitet gör att benet på grund av trycket mellan benvävnad och implantat fjädrar in i implantatets grunda delar. Orunda cylindriska implantat däremot uppvisar ett minskat tryck och minskad initial stabilitet i mjukt ben på grund av att tryck och återfjädring minskar.

Med hjälp av multipla gängingångar kan stigningen ökas och därmed idragningstiden för implantatet förkortas. Således kan man genom uppfinningen erhålla god initial stabilitet och bra grepp vid installation. Dessutom

PCT/SE 98/01982
03 -11- 1998

kan man erhålla en snabbare installation med mindre risk för fippel. Dessutom kan man erhålla en bättre sekundär stabilitet.

FIGURBESKRIVNING

En för närvarande föreslagen utföringsform av en anordning som uppvisar de för uppfinningen signifikativa kännetecknen skall beskrivas i nedanstående under samtidig hänvisning till bifogade ritningar där

figur 1 i vertikalsnitt visar delar av ett ben (tandben) med cirkulär hålupptagning och ett i den cirkulära hålupptagningen iskruvbart implantat med koniska gängor med svag lutning,

figur 2 i vertikalsnitt visar ett implantat applicerat i ett cirkulärt hål i ett delvis visat ben/tandben,

figur 3 i vertikalsnitt visar implantatet enligt figuren 2 i konstruktivt utförande,

figur 4 visar ett tvärsitt A-A av implantatets spets enligt figuren 3,

figur 5 i vertikalvy visar delar av gängsamverkan mellan ett implantat och ett ben/tandben,

figurer 6-9 visar tvärsnitt och ändvy av ett implantat med orunda tvärsnitt,

figurer 10-12 visar implantatsgängor med olika multipla ingångar som ger olika gängstigningar,

figur 13 i perspektiv visar periferiförskjuten orundhet mellan olika gängvarv,

figur 14 i perspektiv snett ovanifrån visar ett komplett utförande enligt figur 13,

figur 15 i perspektiv snett ovanifrån visar en utföringsform med icke periferiförskjuten orundhet,

figur 16 från sidan och i delvis vertikalsnitt visar en implantatskruv relativt hålet i ett tandben,

figur 17 i vertikalsnitt visar ett konkret exempel på gängarrangemang, och

figur 18 visar ett diagram över insättningsmomentet som funktion av insättningsdjupet för två typer av implantat.

DETALJERAD UTFÖRINGSFORM

I figuren 1 visas med 1 ett tandben. I tandbenet är upptaget ett cirkulärt hål 2. Hålupptagningen kan ske på i och för sig känt sätt med i och för sig känd utrustning. Till hålet är ett implantat med gängor med olika koniciteter applicerbar. Delar av nämnda implantat är representerade med delar av implantatets fria ände 3. Nämnda fria ände uppvisar en spetsdel med 3a som övergår i en del 3b. Sistnämnda del uppvisar en

PCT SE98/01982

03 -11- 1998

gänga 3d som är anordnad med en svag konicitet. Med svag konicitet menas här koniciteter där en lutningsvinkel α är av storleksordningen 1° i förhållande till en vertikalaxel 2a för hålet 2 eller en axel parallell med denna axel. Spetsen 3a är försedd med en sig tilldelad gänga 3e som är anordnad med en konicitet som ger en vinkel β som är av storleksordningen 10°. Spetsens 3a äntringsyta eller äntringsdel uppvisar en diameter D´ som väsentligen motsvarar hålets diameter d eller något överstiger sistnämnda diameter d. Håldiametern d kan även väljas i bereonde av benets mjukhetsgrad (kvalitet). Hålets övre och undre delar är angivna med 2c och 2d.

I figuren 2 visas ett konstruktivt utförande av implantatet 3 med tillhörande gänga 3d'. Implantatet är här fullt iskruvat i tandbenshålet 2' och har vid iskruvningen förorsakat upptagning av en gänga 1a i tandbenets hålvägg eller hålets 2' sidovägg 2b. Implantatet uppbär vid sina övre delar infästningsorgan/distansorgan 4 för en speciellt ej visad tandersättning, tandprotes, etc. Organet 4 kan vara försett med fläns 4a med vilken man kan definiera den slutliga igängningsgraden för implantetet så att optimal gänga exponeras mot tandbenet. Såsom framgår av figuren 2 är implantatet i detta fall försett med skär 5 av i och för sig känt slag vid nämnda spets 3a'. Spetsdelen 3a' har en höjd h som utgör 20-30% av den totala höjden H på implantatets gängade del. Genom koniciteten erhålles förbättrad initial stabilitet genom kompression 1a, 1b av benet.

Figuren 3 visar i vertikalsnitt implantatet enligt figuren 2. I denna figur visas en gängad urtagning 6 vars invändiga gänga angivits med 6a. Nämnda distansarrangemang 4 enligt figuren 2 är iskruvbart i nämnda invändiga gänga på i och för sig känt sätt.

p SE 98/01982
03 -11- 1998

Figuren 4 visar att implantatet enligt figurerna 2 och 3 vid nämnda fria ände är utförd med i och för sig kända skär som i figuren 4 angetts med 5a, 5b, 5c och 5d.

Figuren 5 (liksom figuren 2, jfr 1a, 1b) visar att den valda koniciteten för gängan 3d' (jfr figuren 1) etablerar i tandbensmaterialet 1'' en undanträngning av benmaterialet i radiella riktningar R. Koniciteten på gängan 3d' och gängdiametern GD på den lutande gängan är därvid valda så att kontakttrycken P, P' är av väsentligen samma storleksordning eller endast något ökande under implantatets 3' nedskruvning i en riktning 7 i tandbenet 1'' (dess upptagna hål).

I enlighet med uppfinningen kan gängan 3d/3d' enligt ovan vara utförd med orunt/icke cirkulärt/excentriskt gängtvärsnitt och/eller med orunt tvärsnitt för den gänguppbärande kroppen. Figurerna 6,7 och 8 visar olika typer av orundhet och vridningslägen för de olika gängtvärsnitten. De individuella gängtvärsnitten kan vidare ha olika orundheter. I enlighet med figuren 9 kan gängan i spetsen eller implantatets fria ände uppvisa runda eller koncentriska gängtvärsnitt som uppåt övergår i orunda gängsvärsnitt enligt figurerna 6-8. Stor wobblingsfrihet kan på så sätt erhållas vid idragning. I figuren 6 är en gänga angiven med 8. Gängan uppvisar ett antal nedsänkningar 8a, 8b, 8c och 8d. De gängorna i tandbensmaterialet effektuerande delarna med det största radiemåttet är angivna med 8e, 8f, 8g, 8h och 8i. Karakteristiskt för dessa utskjutande delar är att de saknar skarpa hörn, dvs de uppvisar i det aktuella snittet bågformat utformade delar. Detta gäller även i fallet med orund gänguppbärande kropp. Antalet utskjutnings- respektive nedsänkningsdelar kan variera från det i figuren 6

PCT/SE98/01982
03 -11- 1998

angivna, jfr med figurerna 7 och 8. Figuren 9 visar fallet där implantatet vid spetsen uppvisar en cirkulär eller koncentrisk gänga 9.

Figurerna 11 och 12 avser att visa s.k. multipla gängingångar eller multipla gängspiraler som i beroendet av antalet ingångar respektive spiraler ger olika stigningar, jämfört med figur 10 som visar ett utförande med en enda gängingång respektive gängspiral. I figuren 11 är visat ett utförande med två gängingångar eller gängspiraler som effektuerar en stigning som är angiven med Ph', jämfört med stigningen Ph i figur 10. Då principen med dubbla gängspiraler är i och för sig väl förut känd skall den inte beskrivas närmare här. Principen är förut känd från helt andra områden för att lösa helt andra problem. Det kan härvid hänvisas till snäckväxlar som utnyttjar snäckskruvar med multipla gängingångar eller gängspiraler. I figuren 12 är visat ett utförande med tre gängingångar eller gängspiraler som ger en stigning Ph''. Antalet gängingångar/gängspiraler kan kombineras med ett antal skär (jfr figur 4, 5a, 5b, 5c, 5d) så att symmetriska eller balanserade krafter, dvs krafterna balanserar ut varandra, erhålles. Jämför även ovanstående.

Som ovan nämnts kan idragningstiden förkortas för implantat som är utförda med multipla gängingångar. En förkortad installationstid minskar naturligtvis också den dyrbara operationstiden, speciellt vid installation av långa och många implantat. Exempelvis kan det vid installation av sex stycken 18 mm långa implantat, vilket ej är ovanligt vid en s.k. helkäkesoperation, sparas 5 min operationstid om två gängingångar utnyttjas istället för en. Om dessutom hålet behöver förgängas så trefaldigas besparingstiden.

PCT SE 98/01982
03 -11- 1998

Figuren 13 visar ett utförande av implantat där orundheten i de olika gängtvärsnitten förskjutes utefter implantatets längdsträckning L. Respektive gänga 10 är förskjuten i förhållande till intilliggande gänga 11 i vridriktningen. De i ovan omnämnda avfasade hörnen är i detta fall symboliserade med 12. Wobblingsfriheten vid idragning av implantatet i benhålet med verktyg kan på så sätt ytterligare förstärkas, dvs förbättrad rotationsstabilitet erhålles. Installationen blir snabbare och enklare. Dessutom kan utnyttjas små initialt skärande gängskär för att möjliggöra maximal stor gängarea i fastläkningsprocessen. En del av ovanstående utföringsformer blir användbara som utpräglade mjukbensfixturer (jfr alternativen a) och b). Uppfinningen är användbar även i fall där installationen skall ske med hjälp av gängtapp (dvs i två steg).

Figur 14 visar ett komplett implantat med förskjuten orundhet enligt figuren 13 samt en gängad spetsdel 13. Figur 15 visar ett utföringsexempel på icke förskjuten orundhet mellan de olika gängvarven.

Figur 16 visar förhållandet för den valda svaga koniciteten och håldiametern Hd för ett i tandbenet 14 uppborrat hål 15. Vid håldiametern Hd = 3 mm kan väljas värden a och b för koniciteten på kroppen 16 om ca 0,55 mm respektive 0,45 mm. På så sätt erhålles de konstanta eller väsentligen konstanta inbördes trycken (jfr P och P´) enligt ovan.

Koniciteten kan erhållas antingen genom att hela gängprofilens diameter successivt ökar sett från spetsen, eller att gängans bottendiameter eller dess ytterdiameter ökar successivt.

PCT/SE 98/01982
03 -11- 1998

Figur 17 visar en konkret gängbildning 17, 18 i tandbenet 19 med hjälp av fixturen 20.

Figur 18 visar insättningsmomentet som funktion av insättningsdjupet, dels för svagt koniska implantat och dels för cylindriska implantat. Eftersom trycket inte minskar under insättningsförloppet och verkar på en allt större area på implantatet så leder detta till att det svagt koniska implantatet kräver ett allt större insättningsmoment som framgår av figuren. Det större insättningsmomentet är ett mått på den ökade stabiliteten hos implantatet. Cylindriska implantat uppvisar insättningskurvor med konstant eller t.o.m. minskande moment, speciellt vid dåliga benkvaliteter, vilket också framgår av figuren 18.

Uppfinningen är inte begränsad till den i ovan som exempel visade utföringsformen utan kan underkastas modifikationer inom ramen för efterföljande patentkrav och uppfinningstanken.

PCT SE 98/01982
03 -11- 1998

PATENTKRAV.

1. Anordning för att åstadkomma tillförlitlig förankring av gängförsett implantat (3) i benmaterial (1), företrädesvis tandben, i människokroppen, där benmaterialet är försett med upptaget hål (2) i vars sidovägg (2b) är etablerbar en invändig gängbildning (1a) som är samverkbar med en utvändig gängbildning (3d, 3d') på implantatet för implantatets tillförlitliga förankring och fastläkning i benmaterialet, k ä n n e t e c k n a d av ett eller kombinationen av två eller samtliga av följande alternativ:

a) att implantatets gängbildning är anordnad att, speciellt vid mjukt benmaterial, förorsaka en av implantatets iskruvningsgrad i hålet beroende utpressning av benmaterialet i väsentligen radiella riktningar (R), att implantetets gängbildning är anordnad att förorsaka en större utpressning av benmaterialet vid hålets yttre delar (2c) jämfört med hålets inre delar (2d), och att utpressningsgraden därvid är relationsställd till benmaterialets mjukhetsgrad för att effektuera den tillförlitliga förankringen,

b) att implantetets gängbildning åtminstone utefter en del av implantatets längdriktning är tilldelad en ocirkulär eller excentrisk utformning (8a-8i) i syfte att erhålla förbättrad rotationsstabilitet i mjukt/dåligt ben,

c) att implantatet är försett med gängbildning som innefattar parti(-er) med två eller flera gängspiraler (gängingångar) som trots förkortning av iskruvningstiden för implantatet i hålet uppvisar en tät gängbildning som möjliggör effektiv integration med benmaterialet under fastläkningen.

2. Anordning enligt patentkravet 1, k ä n n e t e c k-

SE 98/01982
03 -11- 1998

n a d därav, att i fallet enligt a) implantatets gängbildning är anordnad att åstadkomma att trycket (P, P') mellan benmaterialet och implantatet uppvisar väsentligen konstant eller något ökande värde under den väsentligaste delen av iskruvningsförloppet för implantatet i hålet.

3. Anordning enligt patentkravet 1 eller 2, k ä n n e t e c k n a d därav, att i fallet enligt a) implantatets gängbildning innefattar ett parti (3b) vars gänga (3d) är svagt koniskt avsmalnande mot implantatets fria ände (3a) och sträcker sig utefter den väsentligaste delen eller delarna av implantatets längd (L).

4. Anordning enligt patentkravet 1, 2 eller 3, k ä n n e t e c k n a d därav, att implantatets främre parti (spets) är utförd med en sig tilldelad konisk gänga (3e) som uppvisar en konicitet som väsentligen överstiger koniciteten på den svagt koniska gängan (3d).

5. Anordning enligt något av föregående patentkrav, k ä n n e t e c k n a d därav, att i fallet enligt a) koniciteten på den svagt koniska gängan är vald mellan 0,1-0,4 mm eller uppvisar en lutningsvinkel (α) av ca 0,5-2°, och/eller att gängkoniciteten på gängan vid nämnda parti/spets (3a) är av storleksordningen 0,4-0,8 mm eller med en lutningsvinkel (β) av ca 10-15°, varjämte partiet/spetsen uppvisar en längd eller höjd (h) av ca 10-30% av längden (L) på implantatets gängbildningsdel.

6. Anordning enligt något av föregående patentkrav, k ä n n e t e c k n a d därav, att i fallet a) ett implantat med svag konicitet för gängbildningen utefter implantatets väsentliga längdriktning (L) sam-

SE 98/01982
03 -11- 1998

verkar med ett cirkulärcylindriskt hål (2) i benet (1).

7. Anordning enligt patentkravet 1, k ä n n e t e c k n a d därav, att i fallet enligt b) ocirkulariteten eller excentriciteten är anordnad att väsentligen öka implantatets rotationsstabilitet i implantatets nyss isatta eller fastväxta läge.

8. Anordning enligt patentkravet 7, k ä n n e t e c k n a d därav, att implantatet är anordnat med en minsta diameter (D´) som motsvarar eller är något större, t.ex. 1-5%, än benhålets diameter (d).

9. Anordning enligt patentkravet 1 eller något av patentkraven 7-8, k ä n n e t e c k n a d därav, att implantatets spets eller fria ände uppvisar en rund eller koncentrisk gänga (3e) som successivt övergår i en orund eller excentrisk gänga på implantatets övriga del eller delar.

10. Anordning enligt patentkravet 1 eller något av patentkraven 7-9, k ä n n e t e c k n a d därav, att periferierna på de olika orunda eller excentriska gängtvärsnitten uppvisar avfasade hörn (12) för att motverka skarpa hörn.

11. Anordning enligt patentkravet 1 eller något av patentkraven 7-10, k ä n n e t e c k n a d därav, att orundheten är anordnad så att områden med maximal diameter förskjuts i perifiell led från ett gängvarv (10) till nästa gängvarv (11).

12. Anordning enligt patentkravet 1, k ä n n e t e c k n a d därav, att den i fallet enligt c) är

PCT/SE98/01982
03-11-1998

anordnad att motverka deformation eller sönderbrytning av fina bentrabekler som omger hålet i benet.

13. Anordning enligt patentkravet 1, 11 eller 12, k ä n n e t e c k n a d därav, att antalet gängspiraler/gängingångar är två, tre eller fyra.

14. Anordning enligt patentkravet 1, 11, 12 eller 13, k ä n n e t e c k n a d därav, att antalet gängspiraler/gängingångar är anpassade till antalet skär (5a, 5b, 5c, 5d) på implantatet så att symmetriska skärkrafter uppträder.

15. Anordning enligt patentkravet 1, 11, 12, 13 eller 14, k ä n n e t e c k n a d därav, att på implantatet två gängspiraler är anordnade tillsammans med två eller fyra skär, eller att tre gängspiraler är anordnade tillsammans med tre skär, osv.

PCT SE 98/01982
03 -11- 1998

SAMMANDRAG

I en anordning för att åstadkomma tillförlitlig förankring av gängförsett implantat (3) i tandben är benmaterialet försett med ett upptaget hål (2). I hålets sidovägg (2b) är etablerbar invändig gängbildning som är samverkbar med en utvändig gängbildning (3d) på implantatet. Implantatets gängbildning är anordnad att förorsaka en av implantatets iskruvningsgrad i hålet beroende utpressning av benmaterialet i väsentligen radiella riktningar. Gängbildningen är anordnad att förorsaka större utpressning av benmaterialet vid hålets yttre delar jämfört med hålets inre delar. Utpressningsgraden är relationsställd till benets mjukhetsgrad för att effektuera den tillförlitliga förankringen. Åtminstone utefter en del av implantatets längdriktning kan implantatets gängbildning tilldelas en ocirkulär utformning i syfte att erhålla förbättrad rotationsstabilitet i mjukt/dåligt ben. Implantatet kan även uppvisa två eller flera gängspiraler/gängingångar som förkortar iskruvningstiden för implantatet i hålet och dessutom erbjuder tät gängbildning som möjliggör effektiv integration med benmaterialet under fastläkningen.

Fig. 1

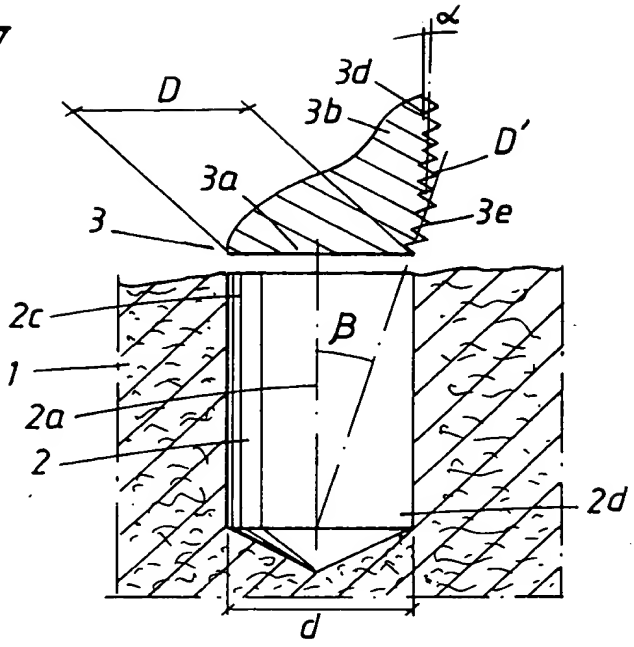


Fig. 2

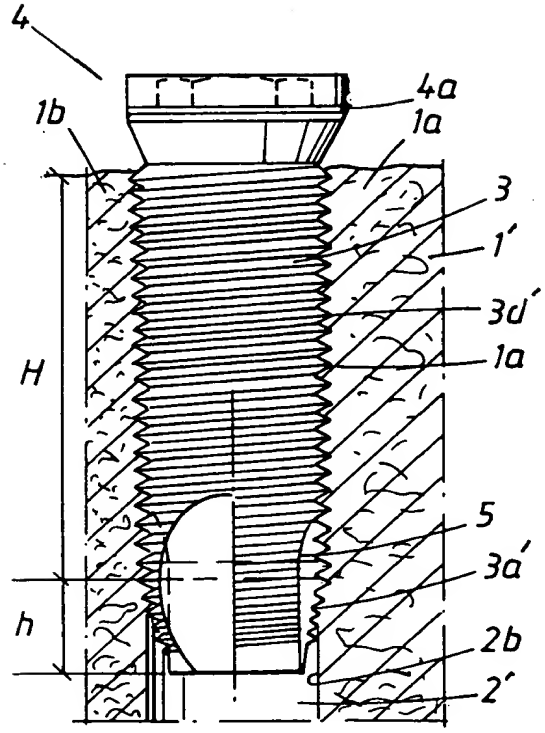


Fig. 3

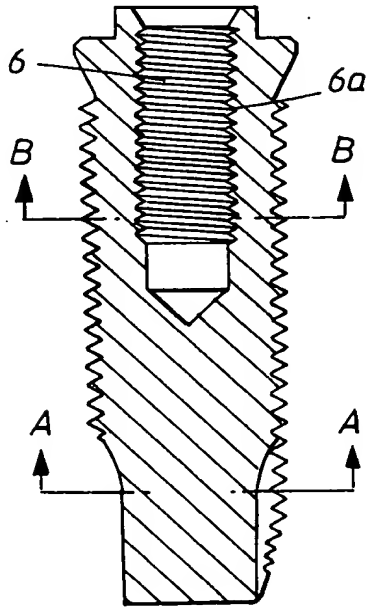


Fig. 4

A–A

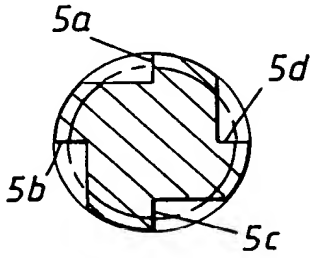


Fig. 5

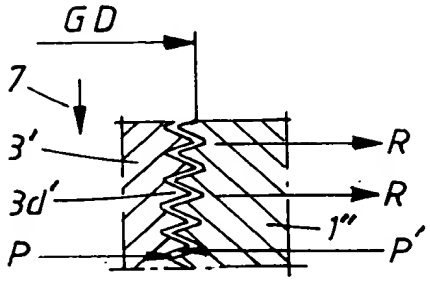


Fig. 6

B–B

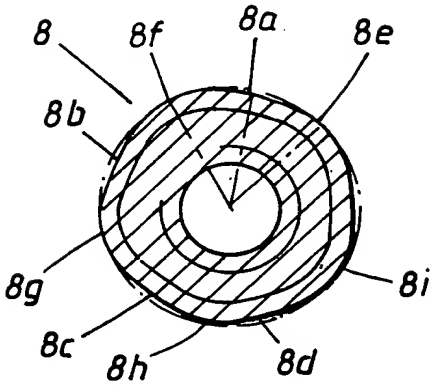


Fig. 7

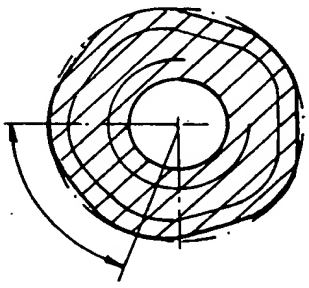


Fig. 8

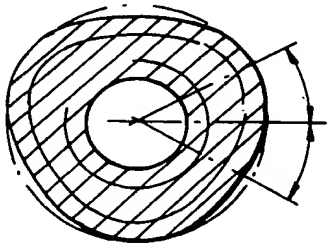


Fig. 9

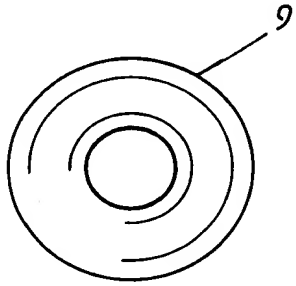


Fig.10

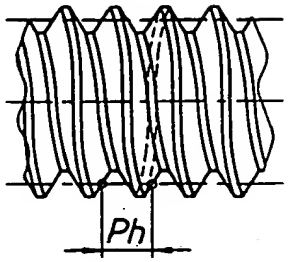


Fig.11

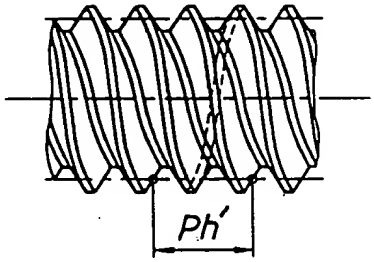


Fig.12

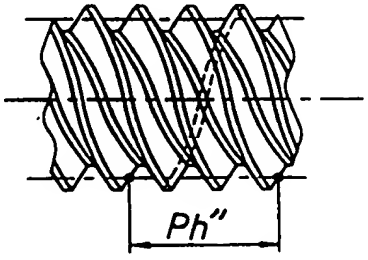


Fig.13

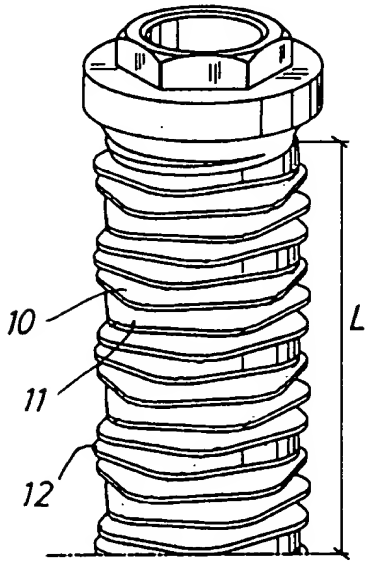


Fig.18

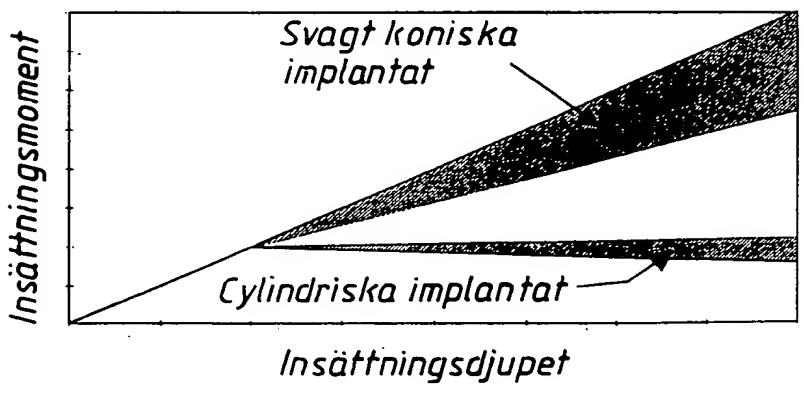


Fig.14

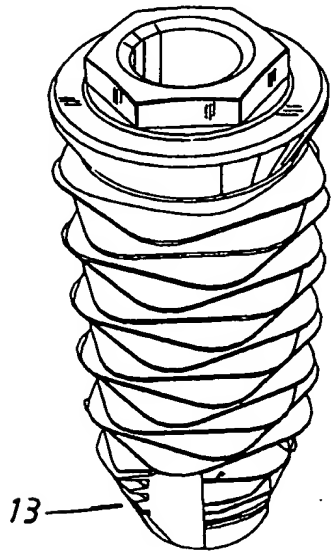


Fig.15

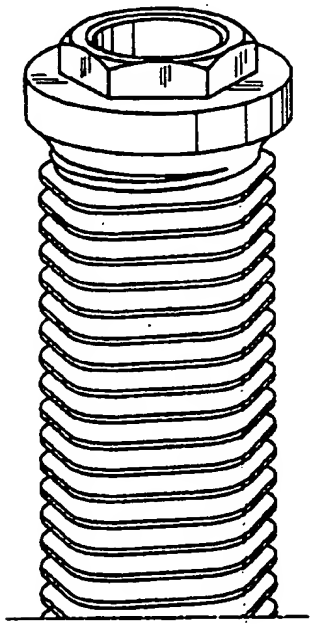


Fig.16

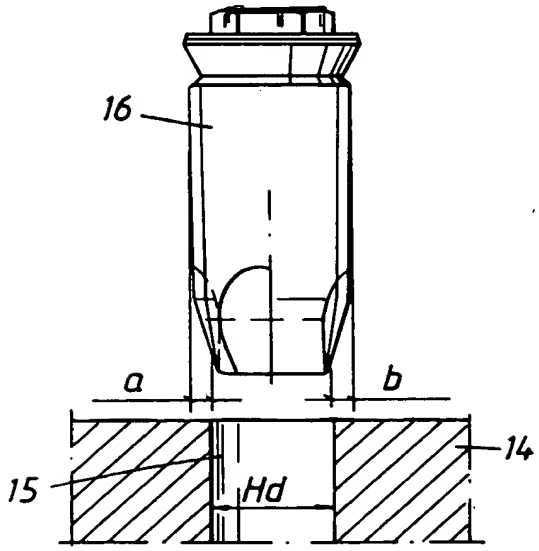
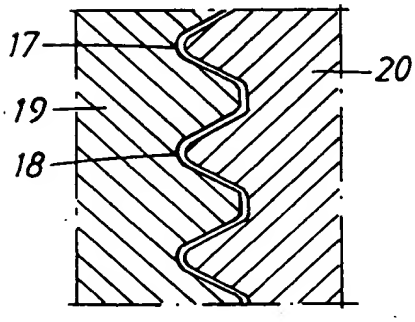


Fig.17



INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/01982

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61C 8/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0282789 A2 (GRAFELMANN, HANS L. PROF.), 21 Sept 1988 (21.09.88) --	1-6
X	EP 0530160 A1 (NOBELPHARMA AB), 3 March 1993 (03.03.93) --	1-6
X	WO 9306786 A1 (RUSSO, GIANNI), 15 April 1993 (15.04.93) --	1-6
X	WO 9725933 A1 (IMPLANT INNOVATIONS, INC.), 24 July 1997 (24.07.97) --	1-11

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search
26 February 1999

Date of mailing of the international search report
06 -03- 1999

Name and mailing address of the ISA/
Swedish Patent Office
Box 5055, S-102 42 STOCKHOLM
Facsimile No. +46 8 666 02 86

Authorized officer
Jack Hedlund
Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/01982

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0263809 A2 (PUTZ, ERICH, DR.), 13 April 1988 (13.04.88) -- --------	1,12-15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/SE 98/01982

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0282789 A2	21/09/88	SE 0282789 T3	
		DE 3708638 A	29/09/88
		US 4863383 A	05/09/89
EP 0530160 A1	03/03/93	AT 136207 T	15/04/96
		CA 2076939 A	28/02/93
		DE 69209592 D,T	19/09/96
		DK 530160 T	05/08/96
		ES 2085612 T	01/06/96
		GR 3019974 T	31/08/96
		JP 2627385 B	02/07/97
		JP 5228162 A	07/09/93
		SE 468154 B,C	16/11/92
		SE 9102451 A	16/11/92
		US 5269685 A	14/12/93
WO 9306786 A1	15/04/93	IT 1253481 B	08/08/95
		IT MO910150 D	00/00/00
WO 9725933 A1	24/07/97	AU 1531697 A	11/08/97
		BR 9704618 A	09/06/98
		EP 0828460 A	18/03/98
		NO 974289 A	17/09/97
EP 0263809 A2	13/04/88	AT 252786 A	15/09/87
		AT 385409 A,B	25/03/88

PATENT CLAIMS

1. Arrangement permitting anchoring of a threaded implant (1) in bone, for example dentine (2), in the human body by means of a screwing instrument (6), the implant having, at its upper part, an anchoring hole (1c) for a unit (screw) intended to secure an element (4) that can be attached to the implant, for example a fixture holder, fixture, spacer, etc., and the centre axis (5a) of the anchoring hole being inclined in relation to the longitudinal axis (1b) of the implant, characterized in that the element (fixture holder, fixture, spacer, etc.) that can be attached by means of the said unit (screw) is provided with means (4d) for cooperation with the instrument (6), and in that the element and its means of cooperation are arranged to permit application of the instrument in a way which ensures that the axis of rotation (6d) of the instrument essentially coincides with a continuation of the longitudinal axis (1b) of the implant.

2. Arrangement according to Patent Claim 1, characterized in that the centre axis (4g) of the element, in the longitudinal extent of the element, essentially coincides with the said continuation, and in that a key grip is arranged concentrically around the centre axis of the element, at the upper part (4a) of the element.

3. Arrangement according to Patent Claim 1 or 2, characterized in that the element has, at its portion cooperating with the upper part (1d) of the implant, an inclined surface (4i) which can be applied against a corresponding inclined surface (1e) on the implant.

4. Arrangement according to any of Patent Claims 1, 2 or 3, characterized in that the element is arranged with a rotationally fixed attachment relative to the

implant, and in that the element, at its portion corresponding to the rotationally fixed attachment, is provided with an inclined recess which is concentric in relation to the anchoring hole (1c), and in that the outer part (5b) of the unit can be at least partially engaged in the said inclined recess (1c).

5. Arrangement according to any of the preceding patent claims, characterized in that the screwing instrument (6) is provided with a locking arrangement, for example comprising a locking screw (7), for locking the instrument to the cooperating means (4d) of the element.

6. Arrangement according to any of the preceding patent claims, characterized in that the element is designed with a key grip with two or more edges, for example four edges, and in that the instrument (6), at its part cooperating with the element so that the latter can be turned, is provided with a recess having straight wall parts, the number of which corresponds to the number of edges.

7. Arrangement according to any of the preceding patent claims, characterized in that the instrument has a shaft-like part (6a) which at its free end supports the members (6c) cooperating with the element, and a handle part (6b) by means of which the rotational movement can be exerted on the instrument when screwing the implant into place.

8. Arrangement according to any of the preceding patent claims, characterized in that the element has a flange and a threaded hole (4e) for securing additional dental members (fixture, spacer, etc.), and, where appropriate, a hole (4f) which extends under the bottom of the said threaded hole, in the transverse direction, and which can be a through-opening.

9. Arrangement permitting anchoring of a threaded implant (1) in bone (2), for example dentine, in the human body by means of a screwing instrument (6), the implant having, at its upper part, an anchoring hole (1c) for a unit (screw) intended to secure an element that can be attached to the implant, for example a fixture holder, fixture, spacer, etc., and the centre axis of the anchoring hole being inclined in relation to the longitudinal axis (1b) of the implant, characterized in that the tightening function exerted by means of the instrument is separate from the securing function exerted by means of the unit by virtue of the fact that the element (4) has a first portion (4b) via which it is anchored by the anchoring unit (5) in the implant, and a second portion (4a) which is separate from the first portion (4b) and which has cooperating means (4d) for the instrument (6).

10. Use of an element, for example fixture holder, fixture, spacer, etc., which can be attached to a threaded implant, where the implant is screwed into a bone (2), for example the dentine, in the human body by means of an instrument (6) and where the implant has an anchoring hole for the securing unit (screw) for the element, the centre axis of the anchoring hole being inclined in relation to the axis of rotation (1b) of the implant, characterized in that the element (4) is used in the screwing operation with the instrument by virtue of the element having means (4d) cooperating with the instrument, to which means (4d) the instrument is applied with its axis of rotation (6d) essentially coinciding with a continuation of the axis of rotation (1b) of the implant.

11. Use according to Patent Claim 10, characterized in that the element (4) is used to form a key grip (4d) for the corresponding key grip (6c) on the instrument (6).

09/509869

PATENT COOPERATION TREATY

PCT

REC'D 17 MAR 2000
WIPO PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 4086 PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE98/01982	International filing date *(day/month/year)* 03.11.1998	Priority date *(day/month/year)* 11.11.1997
International Patent Classification (IPC) or national classification and IPC7 A 61 C 8/00		
Applicant Nobel Biocare AB (publ) et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
04.06.1999	13.03.2000
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88 Telex 17978 PATOREG-S	Authorized officer Jack Hedlund/Els Telephone No. 08-782 25 00

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE98/01982

I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

☐ the international application as originally filed.

☒ the description, pages 1-16, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____.
pages _____, filed with the letter of _____.

☒ the claims, Nos. _____, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. 1-12, filed with the letter of 01.12.1999.
Nos. _____, filed with the letter of _____.

☒ the drawings, ~~sheets~~/fig 1-18, as originally filed,
~~sheets~~/fig _____, filed with the demand
~~sheets~~/fig _____, filed with the letter of _____,
~~sheets~~/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, ~~sheets~~/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE98/01982

V. Resoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-12	YES
	Claims		NO
Inventive step (IS)	Claims	1-12	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

2. Citations and explanations

The claimed invention relates to a threaded implant for obtaining reliable anchoring in bone substance.

The object of the invention is to reduce the friction between bone and implant on insertion of the implant.

This is achieved by an implant, in which the threading is arranged to force the bone substance out in essentially radial directions as a function of the extent to which the implant is screwed into the hole. The implant also has two or more thread spirals / thread entries.

New, amended claims have been filed 01.12.1999. The new claim 1 substantially corresponds to previous claims 1 (alternatives a + c), 3, 6 and 12. The claims are now also directed to a "Threaded implant for obtaining..." instead of "Arrangement for obtaining...". The sub-claims substantially correspond to previous claims 2, 4, 5, 7-11 and 13-15. Specifically, the implant threading has a slight conicity, which cooperates with a cylindrical hole, and effects greater forcing out of the bone at the outer parts of the hole than at the inner parts. The conical threading also has two or more thread spirals that shortens the time for inserting the implant but still provides a tight threading which permits effective bone integration and counteracts deformation or breaking-up of fine bone trabeculae when inserted in soft/weak bone.

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V

The following documents are cited in the search report:

(D1) EP 0282789 A2
(D2) EP 0530160 A1
(D3) WO 9306786 A1
(D4) WO 9725933 A1
(D5) EP 0263809 A2

(D1) - (D4) relates to implants having a threading, which is arranged to force the bone substance out in radial directions. Greater forcing out is effected at the outer parts of the hole than at the inner parts of the hole.

The implant in (D4) is given a non-circular cross section.

(D5) relates to an implant having two thread spirals.

However, none of the documents mention anything about an implant having threading with a slight conicity and also having two or more thread spirals, and none of the documents relates to the problems when inserting an implant into soft/weak bone tissue.

Therefore, the cited documents only disclose the general state of the art, which is not considered to be of particular relevance, and the invention claimed 01.12.1999 is considered to fulfil the requirements of novelty, inventive step and industrial applicability.

TITLE

Arrangement for obtaining reliable anchoring of a threaded implant in bone.

TECHNICAL FIELD

The present invention relates to an arrangement for obtaining reliable anchoring of a threaded implant in bone, preferably dentine, in the human body. The bone in question is in this case provided with a hole in whose side wall it is possible to establish an internal threading which can cooperate with an external threading on the implant for reliable anchoring and healing-in of the implant in the bone substance.

PRIOR ART

Implants with threads, for example self-tapping threads, for insertion/screwing into holes made in the bone/dentine are available in large numbers and designs on the open market and are described in the patent literature. Thus, for example, reference may be made to Swedish Patent Application 9603091-7 filed by the same Applicant filing the present patent application.

In this connection it is known to use different thread formations on implants. Thus, for example, it is already known to use implants with cone-shaped threads and to choose different conicities on one and the same implant. The methods for forming the holes in the bone/dentine are also already well known. In this connection, reference may be made, in purely general terms, to dental treatment by the Brånemark System®.

Some of the threaded implants are cylindrical, while others can have the said conical designs in order to imitate the tooth root which they are intended to replace. The implants are inserted into holes that have been drilled beforehand in the jaw bone. A cylindrical

hole is drilled for cylindrical implants, and for conical implants a conical hole is prepared. The cited method using the Brånemark System® involves securing screw-shaped implants in the jaw bone. After a period of healing-in, normally about 3 - 6 months, the bone has grown in direct contact with the implant and the latter can then be used to support a prosthetic reconstruction. This is in most cases achieved by means of a so-called spacer element being attached to the implant, which can be done by a screw connection. A transfer cap is then attached to the top of the spacer upon so-called impression-taking, and the finished prosthetic reconstruction can thereafter be applied to the spacer.

From the known methods it is already known that good long-term results are obtained if the osteointegration between the bone and the implant can take place with a tight profile and small pitch of the threads in question. During the osteointegration, the bone tissue grows in direct contact with the implant. Upon fitting the implants, the said holes are drilled in the bone with great precision. In this connection it is already known to use tightening instruments which rotate at about 20 - 25 rpm.

In WO 97/25933 (PCT/US97/00332) it has already been proposed, especially in connection with hard dentine, that the body presenting the thread should be made non-circular (asymmetric) in its cross-section.

The purpose of the non-circularity is to reduce the friction between bone and implant on insertion of the implant. This is important mainly in the case of hard bone.

DESCRIPTION OF THE INVENTION

TECHNICAL PROBLEM

The problem with using cylindrical implants in cylindrical holes is that the thread which is in most cases created by the self-tapping tip of the implant is worn away as the implant is screwed in, and with this wearing the thread is widened, mainly at the inlet/mouth of the hole in the bone. This results in the implant having a slightly loose anchoring, especially in weak/soft bone, which means that the implant has a poor initial stability. When using conical implants with a conical preparation, one of the greatest problems is the development of heat which occurs during the conical preparation. Since a conical drill cuts along the whole periphery, relatively great heat is generated, and this negative effect is amplified further by the fact that the cutting geometry of a conical drill becomes worse because a low surface pressure occurs at the periphery of the conical drill. This means that the drill cannot cut proper chips but instead scrapes bone away, and this has a high heat-generating effect. This heat can damage the bone and can lead to the bone nearest the drilled hole dying. This drastically reduces the possibilities of successful osteointegration. The object of the present invention is to solve the above problems among others.

The said use of a screw connection on the implant involves the screwing and unscrewing of screws. This represents a relatively great risk since the implant is subjected to breaking stresses which mean that the implant is at risk of being turned out of its position. This applies in particular if the implants are fitted in bone which is of weak/soft quality. The above unscrewing problems are especially pronounced in the case of implants with a thread which is circularly symmetrical. In most threaded implants, it is of course possible to arrange cutouts at the tip, which are intended both to cut threads and to contribute to the

rotational stability. There are also implants with transverse holes for bone to grow into. A common feature of these known constructions is that the recesses and holes are relatively small when seen in relation to the threaded area of the implant. Since the surface of the recesses or holes is small, deformation or break-up of the ingrown bone can easily take place upon torsional loading. In addition, the holes and recesses are situated at the very front of the tip where in most cases the quality of the bone (its hardness) is poor. There is also an inherent weakness in that the holes and recesses reduce the threaded area of the implant. It must be emphasized here that it is essential to have the greatest possible threaded area for effective transfer of the functional load from the tooth prosthesis or tooth bridge down to the bone. This applies in particular in the case of soft bone.

Another problem with the known implants is that the respective implant, especially in the case of weak/soft bone quality, does not sit with sufficient stability in the bone directly after insertion. When this is the case, microscopic movements can occur between the implant and the surrounding bone tissue, for example when the bone is bent, which can happen when the bone is exposed to mastication loads or when the patient has a conventional tooth prosthesis which presses on the gum above the implant. It is then important for the implant to have sufficient initial stability. Previously known solutions have consisted in introducing changes to the surface, for example using a coating of hydroxyapatite or increasing the surface roughness of the implant and in this way offering increased initial stability and possibly better incorporation of the surrounding bone. A great disadvantage of the proposed solutions has been that it is not possible to predict the long-term success of the implant. There are various scientific articles which have been published concerning the poor long-term

results of implants with a rough surface or with coatings.

An important precondition for being able to implement the abovementioned methods is to create the conditions for obtaining direct bone contact with the implant during the healing-in process. It is essential in this connection to perform meticulous surgery when fitting the implants. The hole for the implant must be drilled with great precision and in this connection it is of the utmost importance that the temperature in the bone does not become too high. These requirements have hitherto meant that both the drilling and the fitting of the implant have been carried out with the hole-forming and tightening instruments being operated at low speed. The speed of rotation which is normally employed when fitting implants is 20 - 25 rpm. This means that the time required for fitting an implant can amount to 1 minute or more. During this time, it is necessary for the surgeon fitting the implant to keep a very steady hand so as to ensure that the fine bone trabeculae surrounding the hole are not deformed or broken up. Wobbling movements of the instrument during tightening pose risks of deformation and break-up. Attempts have been made to solve this problem by providing the implant with an increased thread pitch. Normally, this means that the thread profile is greater and the thread becomes thinner. This thinner thread is disadvantageous in several respects. There are fewer threads and thus an increased stress concentration around each thread crest and also, with a coarser thread profile, a greater difference between the external and internal diameters, which for a given external diameter of the implant leads to a mechanically weaker implant. An alternative solution to this problem would be to increase the speed of the tightening instrument so that the implant rotates more quickly into position. This method also has disadvantages. The temperature of the bone tissue can become too high. Another factor to be taken into

consideration is that a large number of the drilling and tightening instruments available on the market work at a speed which is limited to 20 - 25 rpm.

The invention is intended to solve the last-mentioned problems too.

SOLUTION

The main characteristic of an arrangement according to the invention is that it satisfies one or a combination of two or all of the following features:

a) the implant threading is arranged, particularly in the case of soft bone substance, to force the bone substance out in essentially radial directions as a function of the extent to which the implant is screwed into the hole, the implant threading is arranged to effect greater forcing out of the bone substance at the outer parts of the hole than at the inner parts of the hole, and the degree of forcing out is adapted in relation to the softness of the bone substance in order to achieve the reliable anchoring,

b) along at least part of the longitudinal direction of the implant, the implant threading is given a non-circular or eccentric configuration for the purpose of obtaining improved rotational stability in soft/weak bone,

c) the implant is provided with a threading which comprises one or more portions with two or more thread spirals or thread entries which, despite shortening the time for screwing the implant into the hole, provide a tight threading which permits effective integration with the bone substance during the healing-in process/ osteointegration.

In embodiments according to a) above, the implant threading is arranged to ensure that the pressure between the bone substance and the implant has essentially a constant or only slightly increasing

value during the greater part of the operation of screwing the implant in. The implant threading can also comprise a portion whose thread has a slight conical narrowing towards the free end or tip of the implant and extends along at least the greater part of the length of the implant. In one embodiment, the front portion or tip of the implant can be designed with a conical thread which has a stronger conicity than the other thread or thread parts of the implant. The conicity measured over the diameter of the slightly conical thread can be chosen within the range of 0.1 to 0.4 mm or can have an angle of inclination of about 0.5 - 2°. The thread conicity of the thread of the portion or tip can be of the order of 0.4 - 0.8 mm or can be designed with an angle of inclination of about 10 - 15°. The tip can have a length which is 10 - 30% of the length of the total thread of the implant. In a preferred embodiment, an implant with slight conicity of the main part of its thread is used in a circular cylindrical hole in the bone.

In connection with the features according to b) above, the non-circularity or eccentricity is intended to substantially increase the rotational stability of the implant in the recently inserted (initial) state or the incorporated state of the implant. The non-circularity or eccentricity can also be provided to counteract the breaking up of the thread at the inner parts of the hole. In one embodiment, the implant is arranged with a minimum diameter or cross-sectional width which corresponds to or is only slightly greater, for example 1 - 5% greater, than the diameter of the hole in the bone/dentine. The minimum diameter of the implant is understood to mean the root diameter of the thread at the minimum diameter of the slightly conical portion. The tip or free end of the implant has a circular or concentric thread which, seen from the free end, merges gradually into a non-circular or eccentric thread on the remaining part or parts of the implant. The non-

circularity is provided to ensure that there are no sharp corners, but only bevelled corners. The non-circularity can also be provided so that areas of maximum diameter are displaced in the peripheral direction from one thread turn to the next thread turn. The non-circularity can be provided on the thread-supporting body and/or on the outer portion of each thread.

Embodiments according to c) hereinabove can consist in the arrangement being intended to counteract deformation or breaking-up of free bone trabeculae which surround the hole in the bone. Further features of embodiments can be that the number of thread spirals can be chosen as a function of the desired time for screwing the implant into the hole and thus, for example, the number of thread spirals can be two, three or four. Further features of embodiments are that the number of thread spirals is adapted to the number of cutting edges on the implant so that symmetrical cutting forces are obtained.

ADVANTAGES

By means of what has been proposed above, implants are obtained which have very good properties. The implant can be provided with substantially improved starting properties, which mean that the implant easily "takes threads", even if the initial hole made in the bone is small in relation to the diameter of the implant. Because the pressure between the implant and the thread in the bone does not fall, this permits a gradually increasing advancing force which counteracts any tendency towards breaking the sometimes brittle threads in the bone. The initial stability of the implant in the hole can be improved since the elasticity of the bone means that the bone tissue can completely or partially spring back into the shallower portions of the fixture. After healing in, when new and in most

cases stronger bone has grown in direct contact with the implant, the latter sits with great rotational stability since when slackening the implant it is necessary to break apart large areas of bone seen in relation to the total surface of the implant. This is important in particular in the case of soft bone. The implant thread can be designed with cross sections which are shaped as polygons, preferably with rounded corners, or with 3-sided, 5-sided or 7-sided geometry. This type of non-circular geometry has the property that it has an apparently considerably constant diameter when measured by sliding calliper or micrometer. To improve the starting properties of the implant, so that the implant easily takes threads at the start of screwing in, the implant can be provided with thread cutters. These can be arranged so that they cut at the greatest diameter of the implant, which can be expedient when the implant is conical and the conicity affords a clamping effect.

It is particularly important in the case of soft bone to combine non-circularity with conicity. This conicity can be such that the base diameter gradually increases, or, alternatively, the non-circularity increases in conjunction with a constant or only slightly increasing "internal diameter". The combination of non-circularity and conicity means that because of the pressure between bone tissue and implant the bone springs into the shallower parts of the implant. Non-circular cylindrical implants, by contrast, have a reduced pressure and reduced initial stability in soft bone because the pressure and resilience decrease.

With the aid of multiple thread entries, the pitch can be increased and, in this way, the time for tightening the implant can be shortened. Thus, by means of the invention, it is possible to obtain good initial stability and good gripping upon fitting. It is also possible to obtain more rapid fitting and less risk of

wobble. In addition, it is possible to obtain a better secondary stability.

DESCRIPTION OF THE FIGURES

A presently proposed embodiment of an arrangement having the characteristic features of the invention will be described below with reference to the attached drawings, in which:

Figure 1 shows, in vertical section, parts of a bone (dentine) with a circular hole made in it, and an implant which can be screwed into the circular hole, with conical threads with slight inclination,

Figure 2 shows, in vertical section, an implant applied in a circular hole in bone/dentine, shown partially,

Figure 3 shows, in vertical section, the implant according to Figure 2 in a design embodiment,

Figure 4 shows a cross-section A-A of the implant tip according to Figure 3,

Figure 5 shows, in a vertical view, parts of the thread interaction between an implant and bone/dentine,

Figure 6 to 9 show cross-sections and an end view of an implant with non-circular cross-section,

Figures 10 to 12 show implant threads with different multiple entries which give different thread pitches,

Figure 13 shows, in a perspective view, the peripherally displaced non-circularity between different thread turns,

Figure 14 shows, in a perspective view seen from above, a complete design according to Figure 13,

Figure 15 shows, in a perspective view seen from above, an embodiment with non-circularity and no peripheral displacement thereof,

Figure 16 shows, from the side, and in partial vertical section, an implant screw in relation to the hole in the dentine,

Figure 17 shows, in vertical section, a concrete example of the thread arrangement, and

Figure 18 shows a diagram of the insertion moment as a function of the insertion depth for two types of implants.

DETAILED EMBODIMENT

In Figure 1, reference number 1 designates dentine. A circular hole 2 has been made in the dentine. The hole can be made in a manner known per se using equipment known per se. An implant with threads of different conicities can be applied to the hole. Parts of the said implant are represented by parts of the free end 3 of the implant. The said free end has a tip part 3a which merges into a part 3b. The latter part has a thread 3d which has a slight conicity. Slight conicity is understood here as meaning conicities in which an angle of inclination α is of the order of 1° in relation to a vertical axis 2a of the hole 2 or an axis parallel to this axis. The tip 3a is provided with a thread 3e which is arranged with a conicity which gives an angle β of the order of 10°. The entry surface or entry part of the tip 3a has a diameter D′ which essentially corresponds to the diameter d of the hole or slightly exceeds the said diameter d. The hole diameter d can also be chosen as a function of the softness of the bone (quality). The upper and lower parts of the hole are indicated by 2c and 2d.

Figure 2 shows a structural design of the implant 3 with associated thread 3d'. Here, the implant has been screwed fully into the hole 2' in the dentine and, on being screwed in, has created a thread 1a in the wall of the hole in the dentine or the side wall 2b of the hole 2'. At its upper part, the implant has securing members/spacer members 4 for a special tooth replacement, tooth prosthesis, etc. (not shown). The member 4 can be provided with a flange 4a with which it is possible to define the final degree of threading of the implant so that optimum thread is exposed to the dentine. As can be seen from Figure 2, the implant is in this case provided with cutting edges 5, of a type known per se, at the said tip 3a'. The tip part 3a' has a height h which represents 20 - 30% of the total height H of the threaded part of the implant. By means of the conicity, an improved initial stability is obtained through compression 1a, 1b of the bone.

Figure 3 shows the implant according to Figure 2 in vertical section. In this figure, a threaded recess 6 is shown whose internal thread has been labelled 6a. The said spacer arrangement 4 according to Figure 2 can be screwed into the said internal thread in a manner known per se.

Figure 4 shows that, at the said free end, the implant according to Figures 2 and 3 is designed with cutting edges known per se, which in Figure 4 have been labelled 5a, 5b, 5c and 5d.

Figure 5 (like Figure 2, cf. 1a, 1b) shows that the chosen conicity for the thread 3d' (cf. Figure 1) pushes the dentine substance 1'' out in radial directions R. The conicity of the thread 3d' and the thread diameter GD of the inclined thread are in this case chosen such that the contact pressure P, P' is of essentially the same order or only slightly increases

as the implant 3' is being screwed in a direction 7 into the dentine 1'' (the hole made in it).

In accordance with the invention, the thread 3d/3d' according to the above can be designed with a non-circular/eccentric thread cross-section and/or with a non-circular cross-section for the thread-bearing body. Figures 6, 7 and 8 show different types of non-circularity and positions of rotation of the various thread cross-sections. The individual thread cross-sections can also have different non-circularity. In accordance with Figure 9, the thread at the tip or free end of the implant can have a circular or concentric thread cross-section which at the top merges into a non-circular thread cross-section according to Figures 6 - 8. In this way it is possible to achieve a considerable freedom from wobble during tightening. In Figure 6, one thread is indicated by 8. The thread has a number of depressions 8a, 8b, 8c and 8d. The parts effecting the threads in the dentine with the greatest radial dimensions are indicated by 8e, 8f, 8g, 8h and 8i. The characteristic of these protruding parts is that they do not have sharp corners, i.e. they have parts which are arcuate in cross-section. This applies also in the case of a non-circular thread-bearing body. The number of protrusions and depressions can vary from that indicated in Figure 6, cf. Figures 7 and 8. Figure 9 shows the case in which the implant has a circular or concentric thread 9 at the tip.

Figures 11 and 12 are intended to show so-called multiple thread entries or multiple thread spirals which, depending on the number of entries and spirals, provide different pitches, compare with Figure 10 which shows a design with a single thread entry and thread spiral. Figure 11 shows an embodiment with two thread entries or thread spirals which provide a pitch indicated by Ph', compare with the pitch Ph in Figure 10. As the principle of double thread spirals is

already well known per se, it will not be described in detail here. The principle is already known from completely different areas and for solving completely different problems. In this connection reference may be made to worm gears which use worm screws with multiple thread entries or thread spirals. Figure 12 shows an embodiment with three thread entries or thread spirals which provide a pitch Ph''. The number of thread entries/thread spirals can be combined with a number of cutting edges (cf. Figure 4, 5a, 5b, 5c, 5d) so that symmetrical or balanced forces are obtained, i.e. the forces balance each other out. Compare also with the above.

As has been stated above, the insertion time can be shortened in the case of implants which are designed with multiple thread entries. Of course, a shortened fitting time also reduces the expensive operating time, especially when fitting long and numerous implants. For example, when fitting six implants measuring 18 mm in length, which is not unusual in a so-called whole-jaw operation, 5 minutes of operating time are saved if two thread entries are used instead of one. Moreover, if the hole needs to be pre-threaded, then the saving in time is threefold.

Figure 13 shows an embodiment of the implant in which the non-circularity of the various thread cross-sections is displaced along the longitudinal direction L of the implant. Each thread 10 is displaced in relation to the adjacent thread 11 in the direction of rotation. The abovementioned bevelled corners are in this case indicated by 12. The wobble freedom on insertion of the implant into the hole in the bone with an instrument can in this way be further increased, i.e. improved rotational stability is obtained. Fitting is quicker and simpler. In addition, it is possible to use small initially cutting thread cutters to permit maximum thread area in the healing-in process. Some of

the abovementioned embodiments can be used as soft-bone fixtures (cf. alternatives a) and b)). The invention can also be used in cases where the fitting is to be done with the aid of thread taps (i.e. in two stages).

Figure 14 shows a complete implant with displaced non-circularity according to Figure 13 and a threaded tip part 13. Figure 15 shows an illustrative embodiment in which the non-circularity between the different thread turns is not displaced.

Figure 16 shows the relationship for the chosen slight conicity and the hole diameter Hd for a hole 15 drilled in the dentine 14. With the hole diameter Hd = 3 mm, the chosen values a and b for the conicity of the body 16 can be about 0.55 mm and 0.45 mm, respectively. The constant or essentially constant mutual pressures (cf. P and P') can be achieved in this way.

The conicity can be obtained either by means of the diameter of the whole thread profile gradually increasing as seen from the tip, or by means of the bottom diameter of the thread or its external diameter gradually increasing.

Figure 17 shows a concrete threading 17, 18 in the dentine 19 with the aid of the fixture 20.

Figure 18 shows the insertion moment as a function of the insertion depth, on the one hand for slightly conical implants and on the other hand for cylindrical implants. Since the pressure does not decrease during the insertion procedure and acts on an increasingly greater area of the implant, this means that the slightly conical implant requires an increasingly greater insertion moment, as can be seen from the figure. The greater insertion moment is a measure of the increased stability of the implant. Cylindrical implants have insertion curves with a constant or even

decreasing moment, especially in the case of poor bone quality, as can also be seen from Figure 18.

The invention is not limited to the embodiment shown above by way of example, but can be modified within the scope of the attached patent claims and the inventive concept.

PATENT CLAIMS

1. Arrangement for obtaining reliable anchoring of a threaded implant (3) in bone substance (1), preferably dentine, in the human body, the bone substance being provided with a hole (2) in whose side wall (2b) it is possible to establish an internal threading (1a) which can cooperate with an external threading (3d, 3d') on the implant for reliable anchoring and healing-in of the implant in the bone substance, characterized by one or a combination of two or all of the following alternatives:

a) the implant threading is arranged, particularly in the case of soft bone substance, to force the bone substance out in essentially radial directions (R) as a function of the extent to which the implant is screwed into the hole, the implant threading is arranged to effect greater forcing out of the bone substance at the outer parts (2c) of the hole than at the inner parts (2d) of the hole, and the degree of forcing out is adapted in relation to the softness of the bone substance in order to achieve the reliable anchoring,

b) along at least part of the longitudinal direction of the implant, the implant threading is given a non-circular or eccentric configuration (8a-8i) for the purpose of obtaining improved rotational stability in soft/weak bone,

c) the implant is provided with a threading which comprises a portion (portions) with two or more thread spirals (thread entries) which, despite shortening the time for screwing the implant into the hole, provide a tight threading which permits effective integration with the bone substance during the healing-in process.

2. Arrangement according to Patent Claim 1, characterized in that, in the case according to a), the implant threading is arranged to ensure that the pressure (P, P') between the bone substance and the

implant has essentially a constant or slightly increasing value during the greater part of the operation of screwing the implant into the hole.

3. Arrangement according to Patent Claim 1 or 2, characterized in that in the case according to a), the implant threading comprises a portion (3b) whose thread (3d) has a slight conical narrowing towards the free end (3a) of the implant and extends along most or part of the length (L) of the implant.

4. Arrangement according to Patent Claim 1, 2 or 3, characterized in that the front portion (tip) of the implant is designed with a conical thread (3e) which has a conicity essentially exceeding the conicity of the slightly conical thread (3d).

5. Arrangement according to any of the preceding patent claims, characterized in that in the case according to a), the conicity of the slightly conical thread is chosen between 0.1 - 0.4 mm or has an angle of inclination (α) of about 0.5 - 2°, and/or the thread conicity of the thread at the said portion/tip (3a) is of the order of 0.4 - 0.8 mm or with an angle of inclination (β) of about 10 - 15°, and the portion/tip has a length or height (h) of about 10 - 30% of the length (L) of the threaded part of the implant.

6. Arrangement according to any of the preceding patent claims, characterized in that in case a), an implant with slight conicity of the threading along the longitudinal direction (L) of the implant cooperates with a circular cylindrical hole (2) in the bone (1).

7. Arrangement according to Patent Claim 1, characterized in that in the case according to b), the non-circularity or eccentricity is intended to substantially increase the rotational stability of the

implant in the recently inserted state or the incorporated state of the implant.

8. Arrangement according to Patent Claim 7, characterized in that the implant is arranged with a minimum diameter (D') which corresponds to or is slightly greater, for example 1 - 5% greater, than the diameter (d) of the hole.

9. Arrangement according to Patent Claim 1 or any of Patent Claims 7 - 8, characterized in that the tip or free end of the implant has a circular or concentric thread (3e) which merges gradually into a non-circular or eccentric thread on the remaining part or parts of the implant.

10. Arrangement according to Patent Claim 1 or any of Patent Claims 7 - 9, characterized in that the peripheries of the different non-circular or eccentric thread cross-sections have bevelled corners (12) in order to avoid sharp corners.

11. Arrangement according to Patent Claim 1 or any of Patent Claims 7 - 10, characterized in that the non-circularity is arranged such that areas of maximum diameter are displaced in the peripheral direction from one thread turn (10) to the next thread turn (11).

12. Arrangement according to Patent Claim 1, characterized in that in the case according to c), it is intended to counteract deformation or breaking-up of fine bone trabeculae which surround the hole in the bone.

13. Arrangement according to Patent Claim 1, 11 or 12, characterized in that the number of thread spirals/ thread entries is two, three or four.

14. Arrangement according to Patent Claim 1, 11, 12 or 13, characterized in that the number of thread spirals/thread entries is adapted to the number of cutting edges (5a, 5b, 5c, 5d) on the implant so that symmetrical cutting forces are obtained.

15. Arrangement according to Patent Claim 1, 11, 12, 13 or 14, characterized in that two thread spirals are arranged on the implant together with two or four cutting edges, or in that three thread spirals are arranged together with three cutting edges, etc.

Fig. 1

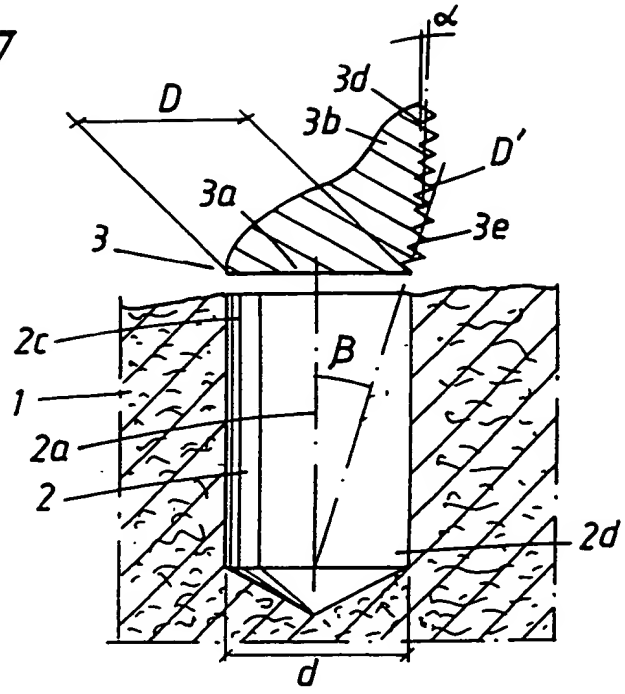


Fig. 2

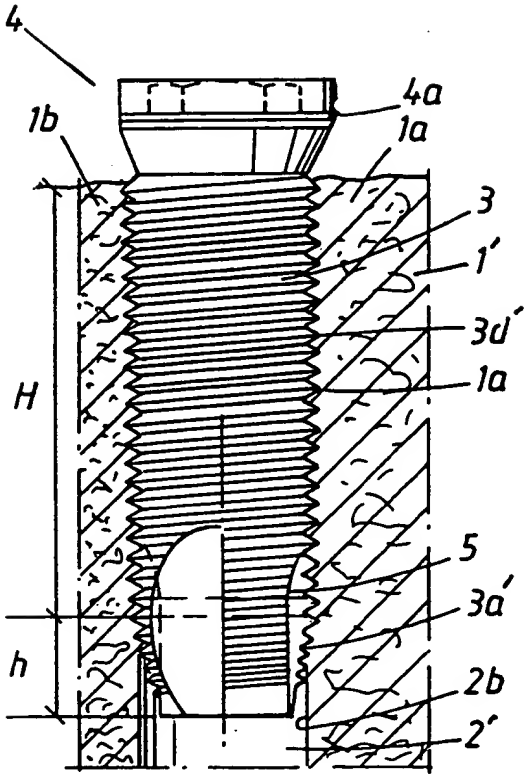
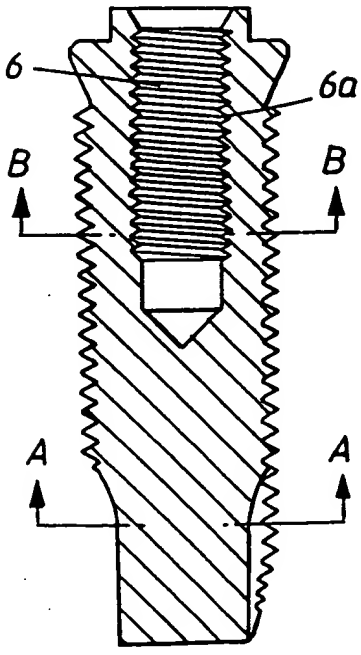


Fig. 3



ABSTRACT

In an arrangement for obtaining reliable anchoring of a threaded implant (3) in dentine, a hole (2) is made in the bone substance. In the side wall (2b) of the hole it is possible to establish an internal threading which can cooperate with an external threading (3d) on the implant. The implant threading is arranged to force the bone substance out in essentially radial directions as a function of the extent to which the implant is screwed into the hole. The threading is arranged to effect greater forcing out of the bone substance at the outer parts of the hole than at the inner parts of the hole. The degree of forcing out is adapted in relation to the softness of the bone in order to achieve the reliable anchoring. Along at least part of the longitudinal direction of the implant, the implant threading can be given a non-circular configuration for the purpose of obtaining improved rotational stability in soft/weak bone. The implant can also have two or more thread spirals/thread entries which shorten the time for screwing the implant into the hole and additionally offer tight threading which permits effective integration with the bone substance during the healing-in process.

Fig.10

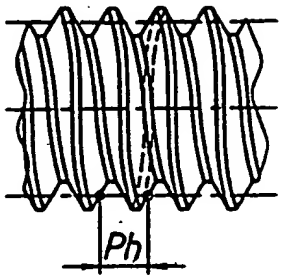


Fig.11

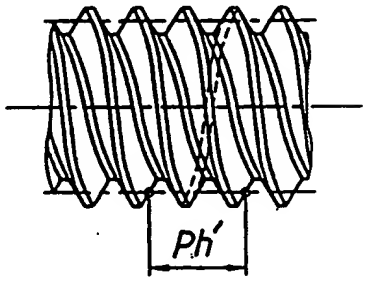


Fig.12

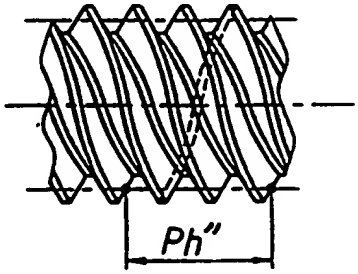


Fig.13

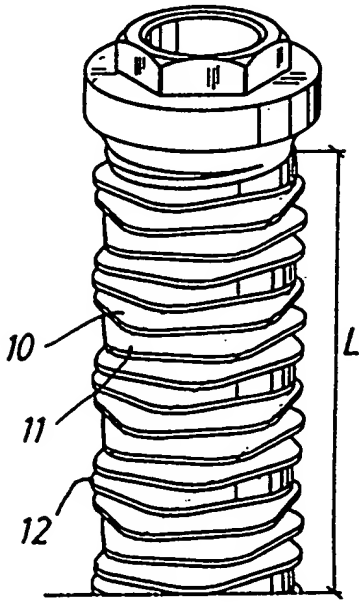


Fig.18

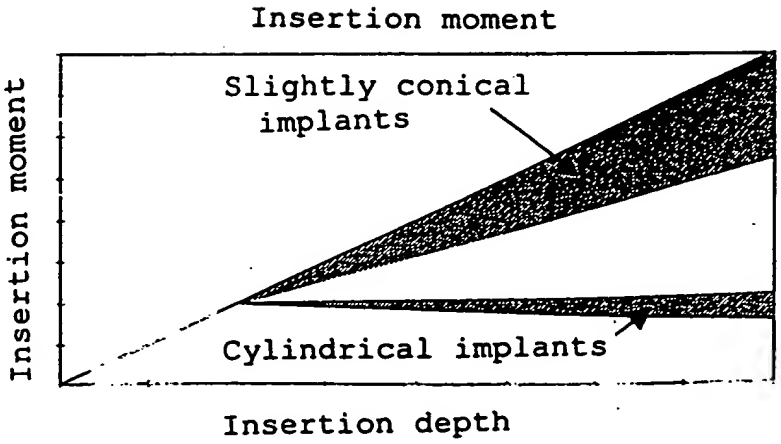


Fig. 4

A-A

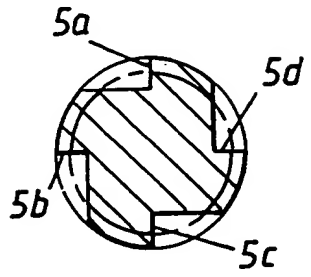


Fig. 5

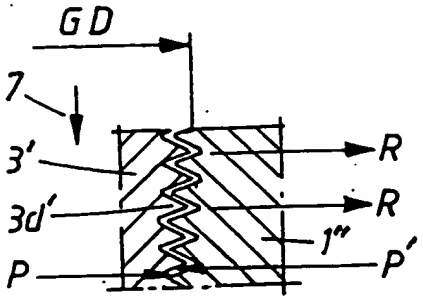


Fig. 6

B-B

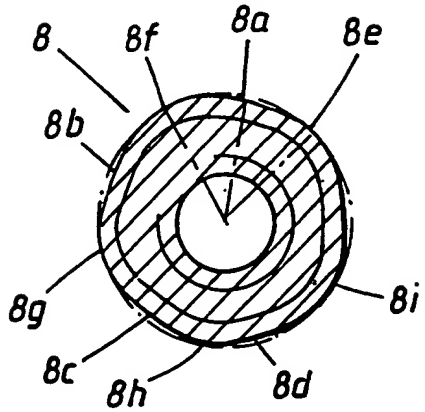


Fig. 7

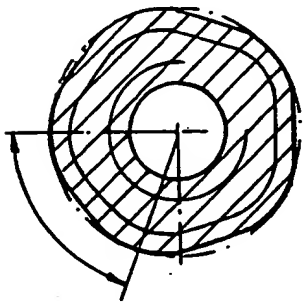


Fig. 8

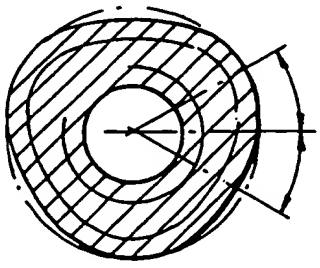


Fig. 9

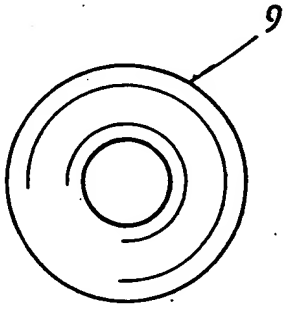


Fig.14

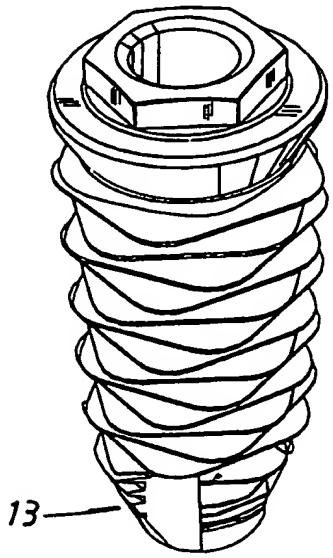


Fig.15

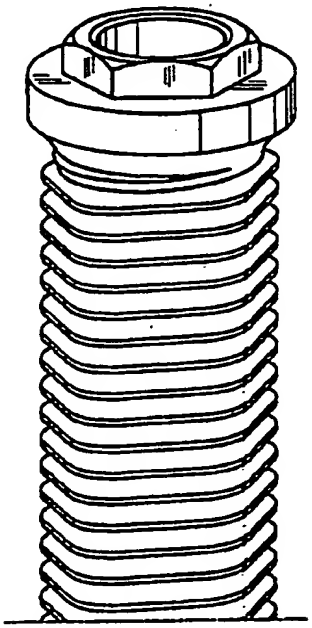


Fig.16

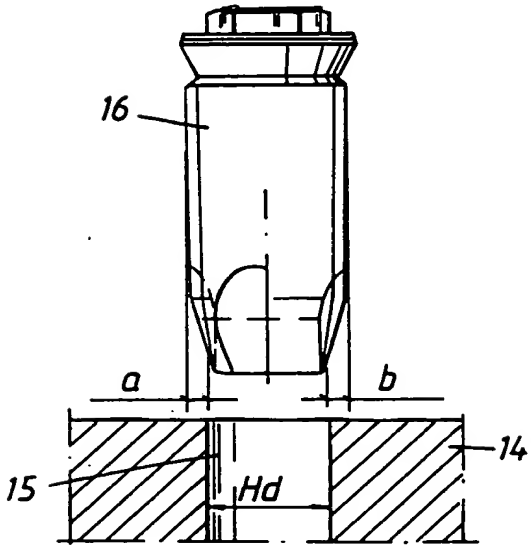
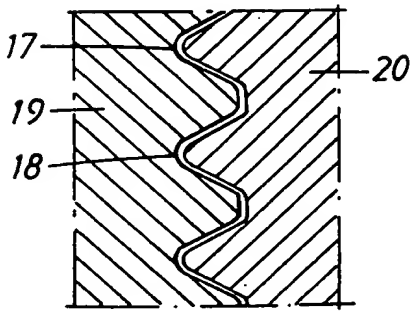


Fig.17



09/509869

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 4086 PCT

Box No. I TITLE OF INVENTION Arrangement for obtaining reliable anchoring of a threaded implant in bone.

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

Nobel Biocare AB (publ)
Box 5190
S-402 26 GÖTEBORG
Sweden

☐ This person is also inventor.

Telephone No. +46(0)31 818800

Facsimile No. +46(0)31 163152

Teleprinter No.

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

CARLSSON, Lennart
Matildebergsgatan 36
S-431 36 ~~GÖTEBORG~~ MÖLNDAL
Sweden

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

OLSSON, Gunnar
Nobel Biocare AB (publ)
Box 5190
S-402 26 GÖTEBORG
Sweden

Telephone No. +46(0)31 818929

Facsimile No. +46(0)31 163152

Teleprinter No.

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

ENGMAN, Fredrik
Häggvägen 19
S-435 37 MÖLNLYCKE
Sweden

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

FROMELL, Roger
Malörtsvägen 11
S-449 33 NÖDINGE
Sweden

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

JÖRNEUS, Lars
Riabergsvägen 7B
S-430 30 FRILLESÅS
Sweden

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

- [ ] Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes: at least one must be marked)*:

Regional Patent

- ☐ AP **ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☐ EA **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☐ OA **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

- ☐ AL Albania
- ☐ AM Armenia
- ☐ AT Austria
- ☒ AU Australia
- ☐ AZ Azerbaijan
- ☐ BA Bosnia and Herzegovina
- ☐ BB Barbados
- ☐ BG Bulgaria
- ☒ BR Brazil
- ☐ BY Belarus
- ☒ CA Canada
- ☐ CH and LI Switzerland and Liechtenstein
- ☐ CN China
- ☐ CU Cuba
- ☐ CZ Czech Republic
- ☐ DE Germany
- ☐ DK Denmark
- ☐ EE Estonia
- ☐ ES Spain
- ☐ FI Finland
- ☐ GB United Kingdom
- ☐ GE Georgia
- ☐ GH Ghana
- ☐ GM Gambia
- ☐ GW Guinea-Bissau
- ☐ HR Croatia
- ☐ HU Hungary
- ☐ ID Indonesia
- ☒ IL Israel
- ☐ IS Iceland
- ☒ JP Japan
- ☐ KE Kenya
- ☐ KG Kyrgyzstan
- ☐ KP Democratic People's Republic of Korea
- ☐ KR Republic of Korea
- ☐ KZ Kazakhstan
- ☐ LC Saint Lucia
- ☐ LK Sri Lanka
- ☐ LR Liberia
- ☐ LS Lesotho
- ☐ LT Lithuania
- ☐ LU Luxembourg
- ☐ LV Latvia
- ☐ MD Republic of Moldova
- ☐ MG Madagascar
- ☐ MK The former Yugoslav Republic of Macedonia
- ☐ MN Mongolia
- ☐ MW Malawi
- ☒ MX Mexico
- ☒ NO Norway
- ☐ NZ New Zealand
- ☒ PL Poland
- ☐ PT Portugal
- ☐ RO Romania
- ☐ RU Russian Federation
- ☐ SD Sudan
- ☐ SE Sweden
- ☐ SG Singapore
- ☐ SI Slovenia
- ☐ SK Slovakia
- ☐ SL Sierra Leone
- ☐ TJ Tajikistan
- ☐ TM Turkmenistan
- ☐ TR Turkey
- ☐ TT Trinidad and Tobago
- ☐ UA Ukraine
- ☐ UG Uganda
- ☒ US United States of America
- ☐ UZ Uzbekistan
- ☐ VN Viet Nam
- ☐ YU Yugoslavia
- ☐ ZW Zimbabwe

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

- ☐ .....
- ☐ .....

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM ☐ Further priority claims are indicated in the Supplemental Box.

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1) 11/11/97 11 Nov. 1997	97 04112-3	SE		
item (2)				
item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s): (1)

** Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)*: ISA / SE

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority)*:

Date *(day/month/year)*	Number	Country *(or regional Office)*
11 November 1997	SE97/01501	SE

Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following **number of sheets**:

request	:	4
description (excluding sequence listing part)	:	16
claims	:	4
abstract	:	1
drawings	:	4
sequence listing part of description	:	
Total number of sheets	:	29

This international application is **accompanied** by the item(s) marked below:

1. ☐ fee calculation sheet
2. ☒ separate signed power of attorney
3. ☒ copy of general power of attorney; reference number, if any: 243
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☐ other *(specify)*: ITS-report

Figure of the drawings which should accompany the abstract: 1b

Language of filing of the international application: Swedish

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Nobel Biocare AB (publ)

/ Gunnar Olsson / AGENT

For receiving Office use only

1. Date of actual receipt of the purported international application:
2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority (if two or more are competent): ISA /
6. ☐ Transmittal of search copy delayed until search fee is paid.

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

PATENT COOPERATION TREATY

1999 -08- 30

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

OLSSON, Gunnar
Nobel Biocare AB (publ)
P.O. Box 5190
S-402 26 Göteborg
SUÈDE

Date of mailing (day/month/year) 16 August 1999 (16.08.99)	
Applicant's or agent's file reference 4086 PCT	**IMPORTANT NOTIFICATION**
International application No. PCT/SE98/01982	**International filing date** (day/month/year) 03 November 1998 (03.11.98)

1. The following indications appeared on record concerning:

[X] the applicant [X] the inventor [ ] the agent [ ] the common representative

Name and Address

CARLSSON, Lennart
Matildebergsgatan 36
S-431 38 Göteborg
Sweden

State of Nationality: SE
State of Residence: SE
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address

* CARLSSON, Lennart
Matildebergsgatan 36
S-431 38 Mölndal
Sweden

State of Nationality: SE
State of Residence: SE
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland** Facsimile No.: (41-22) 740.14.35	Authorized officer Catherine Massetti Telephone No.: (41-22) 338.83.38

002790198

Form PCT/IB/306 (March 1994)

1

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:
OLSSON, Gunnar
Nobel Biocare AB (publ)
P.O. Box 5190
S-402 26 Göteborg
SUÈDE

1999 -06- 02

Date of mailing (day/month/year) 20 May 1999 (20.05.99)	
Applicant's or agent's file reference 4086 PCT	**IMPORTANT NOTICE**

International application No.	**International filing date** (day/month/year)	**Priority date** (day/month/year)
PCT/SE98/01982	03 November 1998 (03.11.98)	11 November 1997 (11.11.97)

Applicant
NOBEL BIOCARE AB (publ) et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
   AU,EP,IL,JP,US

   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
   BR,CA,MX,NO,PL

   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
   20 May 1999 (20.05.99) under No. WO 99/23971

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, **a demand for international preliminary examination** must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the **national phase**, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer
J. Zahra

Telephone No. (41-22) 338.83.38